S. 374

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE SENATE OF THE UNITED STATES

February 4, 1999

Mr. Chafee (for himself, Mr. Graham, Mr. Lieberman, Mr. Specter, Mr. Baucus, Mr. Robb and Mr. Bayh) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Promoting Responsible Managed Care Act of 1999".
- 6 (b) Table of Contents.—The table of contents of
- 7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Preemption; State flexibility; construction.
- Sec. 4. Regulations.

TITLE I—PROMOTING RESPONSIBLE MANAGED CARE

Subtitle A—Grievance and Appeals

- Sec. 101. Definitions and general provisions relating to grievance and appeals.
- Sec. 102. Utilization review activities.
- Sec. 103. Establishment of process for grievances.
- Sec. 104. Coverage determinations.
- Sec. 105. Internal appeals (reconsiderations).
- Sec. 106. External appeals (reviews).

Subtitle B—Consumer Information

- Sec. 111. Health plan information.
- Sec. 112. Health care quality information.
- Sec. 113. Confidentiality and accuracy of enrollee records.
- Sec. 114. Quality assurance.

Subtitle C—Patient Protection Standards

- Sec. 121. Emergency services.
- Sec. 122. Enrollee choice of health professionals and providers.
- Sec. 123. Access to approved services.
- Sec. 124. Nondiscrimination in delivery of services.
- Sec. 125. Prohibition of interference with certain medical communications.
- Sec. 126. Provider incentive plans.
- Sec. 127. Provider participation.
- Sec. 128. Required coverage for appropriate hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer.
- Sec. 129. Promoting good medical practice.

Subtitle D—Enhanced Enforcement Authority

- Sec. 141. Investigations and reporting authority, injunctive relief authority, and increased civil money penalty authority for Secretary of Health and Human Services for violations of patient protection standards.
- Sec. 142. Authority for Secretary of Labor to impose civil penalties for violations of patient protection standards.

TITLE II—PATIENT PROTECTION STANDARDS UNDER THE PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

TITLE III—PATIENT PROTECTION STANDARDS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 302. Enforcement for economic loss caused by coverage determinations.

TITLE IV—PATIENT PROTECTION STANDARDS UNDER THE INTERNAL REVENUE CODE OF 1986

Sec. 401. Amendments to the Internal Revenue Code of 1986.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

Sec. 501. Effective dates.

Sec. 502. Coordination in implementation.

1 SEC. 2. DEFINITIONS.

- 2 (a) Incorporation of General Definitions.—
- 3 The provisions of section 2971 of the Public Health Serv-
- 4 ice Act shall apply for purposes of this section, section
- 5 3, and title I in the same manner as they apply for pur-
- 6 poses of title XXVII of such Act.
- 7 (b) Secretary.—Except as otherwise provided, for
- 8 purposes of this section and title I, the term "Secretary"
- 9 means the Secretary of Health and Human Services, in
- 10 consultation with the Secretary of Labor and the Sec-
- 11 retary of the Treasury, and the term "appropriate Sec-
- 12 retary" means the Secretary of Health and Human Serv-
- 13 ices in relation to carrying out title I under sections 2707
- 14 and 2751 of the Public Health Service Act, the Secretary
- 15 of Labor in relation to carrying out title I under section
- 16 714 of the Employee Retirement Income Security Act of
- 17 1974, and the Secretary of the Treasury in relation to car-
- 18 rying out title I under chapter 100 and section 4980D
- 19 of the Internal Revenue Code of 1986.

1	(c) Additional Definitions.—For purposes of this
2	section and title I:
3	(1) APPLICABLE AUTHORITY.—The term "ap-
4	plicable authority" means—
5	(A) in the case of a group health plan, the
6	Secretary of Health and Human Services and
7	the Secretary of Labor; and
8	(B) in the case of a health insurance issuer
9	with respect to a specific provision of title I, the
10	applicable State authority (as defined in section
11	2791(d) of the Public Health Service Act), or
12	the Secretary of Health and Human Services, if
13	such Secretary is enforcing such specific provi-
14	sion under section $2722(a)(2)$ or $2761(a)(2)$ of
15	the Public Health Service Act.
16	(2) CLINICAL PEER.—The term "clinical peer"
17	means, with respect to a review or appeal, a physi-
18	cian (allopathic or osteopathic) or other health care
19	professional who holds a non-restricted license in a
20	State and who is appropriately credentialed, li-
21	censed, certified, or accredited in the same or similar
22	specialty as manages (or typically manages) the
23	medical condition, procedure, or treatment under re-
24	view or appeal and includes a pediatric specialist

where appropriate; except that only a physician may

- be a clinical peer with respect to the review or appeal of treatment rendered by a physician.
- 3 (3) HEALTH CARE PROVIDER.—The term
 4 "health care provider" includes a physician or other
 5 health care professional, as well as an institutional
 6 provider of health care services.
 - (4) Nonparticipating.—The term "non-participating" means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under a group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.
 - (5) Participating.—The term "participating" means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under a group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.
- 23 SEC. 3. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.
- 24 (a) Continued Applicability of State Law
- 25 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

- (1) In General.—Subject to paragraphs (2) and (3), title I shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or re-quirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or require-ment prevents the application of a requirement of such title.
 - (2) Continued preemption with respect to group health plans.—Nothing in title I shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.
 - (3) Construction with respect to time. Subject to paragraph (2), nothing in title I shall be construed to prohibit a State from establishing, implementing, or continuing in effect any requirement or standard that uses a shorter period of time, than that provided under such title, for any internal or external appeals process to be used by health insurance issuers.
- 24 (b) Rules of Construction.—Nothing in title I 25 (other than section 128) shall be construed as requiring

1	a group health plan or health insurance coverage to pro-
2	vide specific benefits under the terms of such plan or cov-
3	erage.
4	(c) Definitions.—For purposes of this section:
5	(1) State law.—The term "State law" in-
6	cludes all laws, decisions, rules, regulations, or other
7	State action having the effect of law, of any State.
8	A law of the United States applicable only to the
9	District of Columbia shall be treated as a State law
10	rather than a law of the United States.
11	(2) Inclusion of political subdivisions of
12	A STATE.—The term "State" also includes any polit-
13	ical subdivisions of a State or any agency or instru-
14	mentality thereof.
15	(d) Treatment of Religious Nonmedical Pro-
16	VIDERS.—
17	(1) In general.—Nothing in this Act (or the
18	amendments made thereby) shall be construed to—
19	(A) restrict or limit the right of group
20	health plans, and of health insurance issuers of-
21	fering health insurance coverage in connection
22	with group health plans, to include as providers
23	religious nonmedical providers;
24	(B) require such plans or issuers to—

1	(i) utilize medically based eligibility
2	standards or criteria in deciding provider
3	status of religious nonmedical providers;
4	(ii) use medical professionals or cri-
5	teria to decide patient access to religious
6	nonmedical providers;
7	(iii) utilize medical professionals or
8	criteria in making decisions in internal or
9	external appeals from decisions denying or
10	limiting coverage for care by religious non-
11	medical providers; or
12	(iv) compel a participant or bene-
13	ficiary to undergo a medical examination
14	or test as a condition of receiving health
15	insurance coverage for treatment by a reli-
16	gious nonmedical provider; or
17	(C) require such plans or issuers to ex-
18	clude religious nonmedical providers because
19	they do not provide medical or other data other-
20	wise required, if such data is inconsistent with
21	the religious nonmedical treatment or nursing
22	care provided by the provider.
23	(2) Religious nonmedical provider.—For
24	purposes of this subsection, the term "religious non-
25	medical provider" means a provider who provides no

1	medical care but who provides only religious non-
2	medical treatment or religious nonmedical nursing
3	care.
4	SEC. 4. REGULATIONS.
5	The Secretaries of Health and Human Services,
6	Labor, and the Treasury shall issue such regulations as
7	may be necessary or appropriate to carry out this Act.
8	Such regulations shall be issued consistent with section
9	104 of Health Insurance Portability and Accountability
10	Act of 1996. Such Secretaries may promulgate any in-
11	terim final rules as the Secretaries determine are appro-
12	priate to carry out this Act.
13	TITLE I—PROMOTING
14	RESPONSIBLE MANAGED CARE
15	Subtitle A—Grievance and Appeals
16	SEC. 101. DEFINITIONS AND GENERAL PROVISIONS RELAT-
17	ING TO GRIEVANCE AND APPEALS.
18	
	(a) DEFINITIONS.—In this subtitle:
19	(a) Definitions.—In this subtitle:(1) Authorized representative.—The term
19	(1) AUTHORIZED REPRESENTATIVE.—The term
19 20	(1) AUTHORIZED REPRESENTATIVE.—The term "authorized representative" means, with respect to a
19 20 21	(1) Authorized representative" means, with respect to a covered individual, an individual who—
19 20 21 22	(1) AUTHORIZED REPRESENTATIVE.—The term "authorized representative" means, with respect to a covered individual, an individual who— (A) is—

1	cense or certification under applicable
2	State law), or
3	(ii) any legal representative of the
4	covered individual (or, in the case of a de-
5	ceased individual, the legal representative
6	of the estate of the individual),
7	regardless of whether such professional or rep-
8	resentative is affiliated with the plan or issuer
9	involved; and
10	(B) is acting on behalf of the covered indi-
11	vidual with the individual's consent.
12	(2) Coverage Determination.—The term
13	"coverage determination" means any of the follow-
14	ing:
15	(A) A decision by a group health plan or
16	health insurance issuer as to whether to provide
17	benefits or payment for such benefits, including
18	such a decision resulting from the application of
19	utilization review (as defined in section
20	102(a)(3)) or relating to benefits required
21	under section 121 or 128.
22	(B) A decision of a group health plan or
23	health insurance issuer (or the failure of such
24	a plan or issuer) with respect to meeting a re-

1 quirement described in section 122(a), 122(b), 2 122(c), 122(d), 123, or 124. 3 (C) Pursuant to section 104(d)(2), the fail-4 ure of a group health plan or health insurance 5 issuer to provide timely notice under section 6 104(d). (3) COVERED INDIVIDUAL.—The term "covered 7 8 individual" means an individual who is a participant 9 or beneficiary in a group health plan or an enrollee 10 in health insurance coverage offered by a health insurance issuer. 11 (4) Grievance.—The term "grievance" means 12 13 any complaint or dispute other than one involving a 14 coverage determination. 15 (5) Reconsideration.—The term "reconsideration" is defined in section 105(a)(7). 16 (6) Utilization review.—The term "utiliza-17 18 tion review" is defined in section 102(a)(3). 19 (b) Summary of Rights of Individuals.—In accordance with the provisions of this subtitle, a covered in-20 21 dividual has the following rights with respect to a group health plan and with respect to a health insurance issuer in connection with the provision of health insurance cov-

erage:

1	(1) The right to have grievances between the
2	covered individual and the plan or issuer heard and
3	resolved as provided in section 103.
4	(2) The right to a timely coverage determina-
5	tion as provided in section 104.
6	(3) The right to request expedited treatment of
7	a coverage determination as provided in section
8	104(c).
9	(4) If dissatisfied with any part of a coverage
10	determination, the following appeal rights:
11	(A) The right to a timely reconsideration
12	of an adverse coverage determination as pro-
13	vided in section 105.
14	(B) The right to request expedited treat-
15	ment of such a reconsideration as provided in
16	section 105(c).
17	(C) If, as a result of a reconsideration of
18	the adverse coverage determination, the plan or
19	issuer affirms, in whole or in part, its adverse
20	coverage determination, the right to request
21	and receive a review of, and decision on, such
22	determination by a qualified external appeal en-
23	tity as provided in section 106.

(c) Requirements.—

1	(1) Procedures.—A group health plan, and a
2	health insurance issuer in connection with the provi-
3	sion of health insurance coverage shall, with respect
4	to the provision of benefits under such plan or
5	coverage—
6	(A) establish and maintain—
7	(i) grievance procedures in accordance
8	with section 103;
9	(ii) procedures for coverage deter-
10	minations consistent with section 104; and
11	(iii) appeals procedures for adverse
12	coverage determinations in accordance with
13	sections 105 and 106; and
14	(B) provide for utilization review consistent
15	with section 102.
16	(2) Delegation.—A group health plan or a
17	health insurance issuer in connection with the provi-
18	sion of health insurance coverage that delegates any
19	of its responsibilities under this subtitle to another
20	entity or individual through which the plan or issuer
21	provides health care services shall ultimately be re-
22	sponsible for ensuring that such entity or individual
23	satisfies the relevant requirements of this subtitle.
24	SEC. 102. UTILIZATION REVIEW ACTIVITIES.
25	(a) Compliance With Requirements.—

- 1 (1) In General.—A group health plan, and a
 2 health insurance issuer in connection with the provi3 sion of health insurance coverage, shall conduct utili4 zation review activities in connection with the provi5 sion of benefits under such plan or coverage only in
 6 accordance with a utilization review program that
 7 meets the requirements of this section.
 - (2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.
 - (3) Utilization review defined.—For purposes of this section, the terms "utilization review" and "utilization review activities" mean procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.
 - (b) Written Policies and Criteria.—

(1) Written Policies.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) Use of written criteria.—

- (A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed pursuant to the program with the input of appropriate physicians. Such criteria shall include written clinical review criteria described in section 114(b)(4)(B).
- (B) Continuing use of standards in Retrospective review.—If a health care service has been specifically pre-authorized or approved for a covered individual under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the individual during the same course of treatment.

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) Administration by Health care professionals.—

1	(A) IN GENERAL.—A utilization review
2	program shall be administered by qualified
3	health care professionals who shall oversee re-
4	view decisions.
5	(B) HEALTH CARE PROFESSIONAL DE-
6	FINED.—In this section, the term "health care
7	professional" means a physician or other health
8	care practitioner licensed, accredited, or cer-
9	tified to perform specified health services con-
10	sistent with State law.
11	(2) Use of qualified, independent per-
12	SONNEL.—
13	(A) IN GENERAL.—A utilization review
14	program shall provide for the conduct of utiliza-
15	tion review activities only through personnel
16	who are qualified and, to the extent required,
17	who have received appropriate training in the
18	conduct of such activities under the program.
19	(B) PEER REVIEW OF SAMPLE OF AD-
20	verse clinical determinations.—Such a
21	program shall provide that clinical peers (as de-
22	fined in section $2(c)(2)$ shall evaluate the clini-
23	cal appropriateness of at least a sample of ad-

verse clinical determinations.

1	(C) Prohibition of contingent com-
2	PENSATION ARRANGEMENTS.—Such a program
3	shall not, with respect to utilization review ac-
4	tivities, permit or provide compensation or any-
5	thing of value to its employees, agents, or con-
6	tractors in a manner that—

- (i) provides direct or indirect incentives for such persons to make inappropriate review decisions; or
- (ii) is based, directly or indirectly, on the quantity or type of adverse determinations rendered.
- (D) Prohibition of conflicts.—Such a program shall not permit a health care professional who provides health care services to a covered individual to perform utilization review activities in connection with the health care services being provided to the individual. A group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, may not retaliate against a covered individual or health care provider based on such individual's or provider's use of, or participation in, the utilization review program under this section.

- (3) Accessibility of review.—Such a program shall provide that appropriate personnel performing utilization review activities under the program are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.
 - (4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to a covered individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.
 - (5) LIMITATION ON INFORMATION REQUESTS.—Such a program shall provide that information shall be required to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.
 - (6) REVIEW OF PRELIMINARY UTILIZATION RE-VIEW DECISION.—Such a program shall provide that a covered individual who is dissatisfied with a preliminary utilization review decision has the opportunity to discuss the decision with, and have such

- decision reviewed by, the medical director of the plan
- 2 or issuer involved (or the director's designee) who
- 3 has the authority to reverse the decision.

4 SEC. 103. ESTABLISHMENT OF PROCESS FOR GRIEVANCES.

- 5 (a) Establishment.—A group health plan, and a
- 6 health insurance issuer in connection with the provision
- 7 of health insurance coverage, shall provide meaningful
- 8 procedures for timely hearing and resolution of grievances
- 9 brought by covered individuals regarding any aspect of the
- 10 plan's or issuer's services, including a decision not to expe-
- 11 dite a coverage determination or reconsideration under
- 12 section 104(c)(4)(B)(ii)(II) or 105(c)(4)(B)(ii)(II).
- 13 (b) Guidelines.—The grievance procedures re-
- 14 quired under subsection (a) shall meet all guidelines estab-
- 15 lished by the appropriate Secretary.
- 16 (c) Distinguished From Coverage Determina-
- 17 Tions and Appeals.—The grievance procedures required
- 18 under subsection (a) shall be separate and distinct from
- 19 procedures regarding coverage determinations under sec-
- 20 tion 104 and reconsiderations under section 105 and ex-
- 21 ternal reviews by a qualified external appeal entity under
- 22 section 106 (which address appeals of coverage determina-
- 23 tions).
- 24 SEC. 104. COVERAGE DETERMINATIONS.
- 25 (a) Requirement.—

- 1 (1) Responsibilities.—A group health plan, 2 and a health insurance issuer in connection with the 3 provision of health insurance coverage, shall establish and maintain procedures for making timely cov-5 erage determinations (in accordance with the re-6 quirements of this section) regarding the benefits a 7 covered individual is entitled to receive from the plan 8 or issuer, including the amount of any copayments, 9 deductibles, or other cost sharing applicable to such 10 benefits. Under this section, the plan or issuer shall 11 have a standard procedure for making such deter-12 minations, and procedures for expediting such deter-13 minations in cases in which application of the stand-14 ard deadlines could seriously jeopardize the covered 15 individual's life, health, or ability to regain or main-16 tain maximum function or (in the case of a child 17 under the age of 6) development.
 - (2) Parties who may request coverage determination relating to a covered individual and are parties to such determination:
 - (A) The covered individual.
 - (B) Any provider or other person acting on behalf of the covered individual with the individual's consent.

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1 (3) EFFECT OF COVERAGE DETERMINATION.—
2 A coverage determination is binding on all parties
3 unless it is reconsidered pursuant to section 105 or
4 reviewed pursuant to section 106.

(b) Notice of Coverage Determinations.—

- (1) In General.—In the case of a request for a coverage determination, the group health plan or health insurance issuer shall provide notice pursuant to subsection (c) to the person submitting the request of its determination as expeditiously as the health condition of the covered individual involved requires, but in no case later than deadline established under paragraph (2) or (3) (as the case may be) in the case of certain coverage determinations described in such paragraphs.
- (2) DEADLINE FOR COVERAGE DETERMINATIONS INVOLVING PRIOR AUTHORIZATION SERVICES AND CONTINUED CARE.—In the case of a coverage determination described in section 101(a)(2)(A) involving the prior authorization of health care items and services for an individual or authorization for continued or extended health care services for an individual, or additional services for an individual undergoing a course of continued treatment prescribed by a health care provider, the deadline established

1	under this paragraph is 3 business days after the
2	date of receipt of information that is reasonably nec-
3	essary to make such determination.
4	(3) Deadline for previously provided
5	SERVICES.—In the case of a coverage determination
6	(as so described) involving retrospective review of
7	health care services previously provided for an indi-
8	vidual, the deadline established under this paragraph
9	is 30 days of the date of receipt of information that
10	is reasonably necessary to make such determination.
11	(c) Notice of Coverage Determinations.—
12	(1) Requirement.—
13	(A) In general.—A group health plan or
14	health insurance issuer that makes a coverage
15	determination that—
16	(i) is completely favorable to the cov-
17	ered individual shall provide the party sub-
18	mitting the request for the coverage deter-
19	mination with notice of such determina-
20	tion; or
21	(ii) is adverse, in whole or in part, to
22	the covered individual shall provide such
23	party with written notice of the determina-
24	tion, including the information described in
25	subparagraph (B).

1	(B) Content of Written Notice.—A
2	written notice under subparagraph (A)(ii)
3	shall—
4	(i) provide the specific reasons for the
5	determination (including, in the case of a
6	determination relating to utilization review,
7	the clinical rationale for the determination)
8	in clear and understandable language;
9	(ii) include notice, in clear and under-
10	standable language, of the availability of
11	the clinical review criteria relied upon in
12	making the coverage determination;
13	(iii) describe, in clear and understand-
14	able language, the reconsideration and re-
15	view processes established to carry out sec-
16	tions 105 and 106, including the right to,
17	and conditions for, obtaining expedited
18	consideration of requests for reconsider-
19	ation or review; and
20	(iv) comply with any other require-
21	ments specified by the appropriate Sec-
22	retary.
23	(2) Failure to provide timely notice.—
24	Any failure of a group health plan or health insur-
25	ance issuer to provide a covered individual with

- timely notice of a coverage determination as specified in this section shall constitute an adverse coverage determination and a timely request for a reconsideration with respect to such determination shall be deemed to have been made pursuant to the section 105(a)(2).
- 7 (3) Provision of oral notice with writ-8 TEN CONFIRMATION IN CASE OF EXPEDITED TREAT-9 MENT.—If a group health plan or health insurance 10 issuer grants a request for expedited treatment 11 under subsection (c), the plan or issuer may first 12 provide notice of the coverage determination orally 13 within the deadlines established under subsection 14 (b)(3) and then shall mail written confirmation of 15 the determination within 2 business days of the date 16 of oral notification.

17 SEC. 105. INTERNAL APPEALS (RECONSIDERATIONS).

18 (a) Requirement.—

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(1) Responsibilities.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain procedures for making timely reconsiderations of coverage determinations in accordance with this section. Under this section, the plan or issuer shall have a standard procedure for making

- such determinations, and procedures for expediting such determinations in cases in which application of the standard deadlines could seriously jeopardize the covered individual's life, health, or ability to regain or maintain maximum function or (in the case of a child under the age of 6) development.
- (2) Parties who may request reconsideration may request a reconsideration of the determination under this section. Such party shall submit an oral or written request directly with the group health plan or health insurance issuer that made the determination. The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal with the group health plan or health insurance issuer involved.

(3) Deadline for filing request.—

- (A) In General.—Except as provided in subparagraph (B), a party to a coverage determination shall submit the request for a reconsideration within 60 calendar days from the date of the written notice of the coverage determination.
- (B) Extending time for filing request.—Such a party may submit a written re-

quest to the plan or issuer to extend the deadline specified in subparagraph (A). If such a party demonstrates in the request for the extension good cause for such extension, the plan or issuer may extend the deadline.

(4) Parties to the reconsideration.—

- (A) In General.—The parties to the reconsideration are the parties to the coverage determination, as described in section 104(a)(2), and any other provider or entity (other than the plan or issuer) whose rights with respect to the coverage determination may be affected by the reconsideration (as determined by the entity that conducts the reconsideration).
- (B) Opportunity to submit evidence.—A group health plan and a health insurance issuer shall provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. The plan or issuer shall inform the parties of the conditions for submitting the evidence, especially any time limitations.

- 1 (5) EFFECT OF RECONSIDERATION.—A decision 2 of a plan or issuer after reconsideration is binding 3 on all parties unless it is reviewed pursuant to sec-4 tion 106.
 - (6) LIMITATION ON CONDUCTING RECONSIDER-ATION.—In conducting the reconsideration under this subsection, the following rules shall apply:
 - (A) The person or persons conducting the reconsideration shall not have been involved in making the underlying coverage determination that is the basis for such reconsideration.
 - (B) If the issuer involved in the reconsideration is the plan's or issuer's denial of coverage based on a lack of medical necessity, a clinical peer (as defined in section 2(c)(2)) shall make the reconsidered determination.
 - (7) RECONSIDERATION DEFINED.—In this subtitle, the term "reconsideration" means a review under this section of a coverage determination that is adverse to the covered individual involved, or of the imposition of a limitation that is prohibited under section 129, including a review of the evidence and findings upon which it was based and any other evidence the parties submit or the group health plan or health insurance issuer obtains.

(b) DETERMINATION BY DEADLINE.—

(1) In GENERAL.—In the case of a request for a reconsideration, the group health plan or health insurance issuer shall provide notice pursuant to subsection (d) to the person submitting the request of its determination as expeditiously as the health condition of the covered individual involved requires, but in no case later than the deadline established under paragraph (2) or, if a request for expedited treatment of a reconsideration is granted under subsection (c), the deadline established under paragraph (3).

(2) STANDARD DEADLINE.—

- (A) IN GENERAL.—The deadline established under this paragraph is, subject to subparagraph (B)—
 - (i) in the case of a reconsideration regarding a coverage determination described in section 104(b)(2), 30 calendar days after the date the plan or issuer receives the request for the reconsideration, or
 - (ii) in other cases, 60 days after such date.

1	(B) Extension.—The plan or issuer may
2	extend the deadline under subparagraph (A) by
3	up to 14 calendar days if—
4	(i) the covered individual (or an au-
5	thorized representative of the individual)
6	requests the extension; or
7	(ii) the plan or issuer justifies to the
8	applicable authority a need for additional
9	information to make the reconsideration
10	and how the delay is in the interest of the
11	covered individual.
12	(3) Expedited treatment deadline.—
13	(A) In general.—The deadline estab-
14	lished under this paragraph is, subject to sub-
15	paragraphs (B) and (C), 72 hours after the
16	date the plan or issuer receives the request for
17	the expedited treatment under subsection (d).
18	(B) Extension.—The plan or issuer may
19	extend the deadline under subparagraph (A) by
20	up to 5 calendar days if—
21	(i) the covered individual (or an au-
22	thorized representative of the individual)
23	requests the extension; or
24	(ii) the plan or issuer justifies to the
25	applicable authority a need for additional

information to make the reconsideration and how the delay is in the interest of the covered individual.

> (\mathbf{C}) How INFORMATION FROM NON-PARTICIPATING PROVIDERS AFFECTS DEAD-LINES FOR EXPEDITED RECONSIDERATIONS.— In the case of a group health plan or health insurance issuer that requires medical information from nonparticipating providers in order to make a reconsideration, the deadline specified under subparagraph (A) shall begin when the plan or issuer receives such information. Nonparticipating providers shall make reasonable and diligent efforts to expeditiously gather and forward all necessary information to the plan or issuer in order to receive timely payment.

(c) Expedited Treatment.—

- (1) Request for expedited treatment.—A covered individual (or an authorized representative of the individual) may request that the plan or issuer expedite a reconsideration involving the issues described in section 101(a)(2).
- (2) Who may request.—To request expedited treatment of a reconsideration, a covered individual (or an authorized representative of the individual)

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shall submit an oral or written request directly to
the plan or issuer (or, if applicable, to the entity
that the plan or issuer has designated as responsible
for making the decision relating to the reconsideration).

(3) Provider support.—

- (A) IN GENERAL.—A physician or other health care provider may provide oral or written support for a request for expedited treatment under this subsection.
- (B) Prohibition of Punitive action.—
 A group health plan and a health insurance issuer in connection with the provision of health insurance coverage shall not take or threaten to take any punitive action against a physician or other health care provider acting on behalf or in support of a covered individual seeking expedited treatment under this subsection.
- (4) Processing of Requests.—A group health plan and a health insurance issuer in connection with the provision of health insurance coverage shall establish and maintain the following procedures for processing requests for expedited treatment of reconsiderations:

- 1 (A) An efficient and convenient means for 2 the submission of oral and written requests for 3 expedited treatment. The plan or issuer shall 4 document all oral requests in writing and main-5 tain the documentation in the case file of the 6 covered individual involved.
 - (B) A means for deciding promptly whether to expedite a reconsideration, based on the following requirements:
 - (i) For a request made or supported by a physician, the plan or issuer shall expedite the reconsideration if the physician indicates that applying the standard deadline under subsection (b)(2) for making the reconsideration determination could seriously jeopardize the covered individual's life, health, or ability to regain or maintain maximum function or (in the case of a child under the age of 6) development.
 - (ii) For another request, the plan or issuer shall expedite the reconsideration if the plan or issuer determines that applying such standard deadline for making the reconsideration determination could seriously jeopardize the covered individual's life,

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1	health, or ability to regain or maintain
2	maximum function or (in the case of a
3	child under the age of 6) development.
4	(5) Actions following denial of request
5	FOR EXPEDITED TREATMENT.—If a group health
6	plan or a health insurance issuer in connection with
7	the provision of health insurance coverage denies a
8	request for expedited treatment of a reconsideration
9	under this subsection, the plan or issuer shall—
10	(A) make the reconsideration determina-
11	tion within the standard deadline otherwise ap-
12	plicable; and
13	(B) provide the individual submitting the
14	request with—
15	(i) prompt oral notice of the denial of
16	the request, and
17	(ii) within 2 business days a written
18	notice that—
19	(I) explains that the plan or
20	issuer will process the reconsideration
21	request within the standard deadlines;
22	(II) informs the requester of the
23	right to file a grievance if the re-
24	quester disagrees with the plan's or

1	issuer's decision not to expedite the
2	reconsideration; and
3	(III) provides instructions about
4	the grievance process and its time-
5	frames.
6	(6) ACTION ON ACCEPTED REQUEST FOR EXPE-
7	DITED TREATMENT.—If a group health plan or
8	health insurance issuer grants a request for expe-
9	dited treatment of a reconsideration, the plan or
10	issuer shall make the reconsideration determination
11	and provide the notice under subsection (d) within
12	the deadlines specified under subsection (b)(3).
13	(d) Notice of Decision in Reconsiderations.—
14	(1) Requirement.—
15	(A) IN GENERAL.—A group health plan or
16	health insurance issuer that makes a decision in
17	the reconsideration that—
18	(i) is completely favorable to the cov-
19	ered individual shall provide the party sub-
20	mitting the request for the reconsideration
21	with notice of such decision; or
22	(ii) is adverse, in whole or in part, to
23	the covered individual shall—
24	(I) provide such party with writ-
25	ten notice of the decision, including

1	the information described in subpara-
2	graph (B), and
3	(II) prepare the case file (includ-
4	ing such notice) for the covered indi-
5	vidual involved, to be available for
6	submission (if requested) under sec-
7	tion 106(a).
8	(B) CONTENT OF WRITTEN NOTICE.—The
9	written notice under subparagraph (A)(ii)(I)
10	shall—
11	(i) provide the specific reasons for the
12	decision in the reconsideration (including,
13	in the case of a decision relating to utiliza-
14	tion review, the clinical rationale for the
15	decision) in clear and understandable lan-
16	guage;
17	(ii) include notice of the availability of
18	the clinical review criteria relied upon in
19	making the decision;
20	(iii) describe the review processes es-
21	tablished to carry out sections 106, includ-
22	ing the right to, and conditions for, obtain-
23	ing expedited consideration of requests for
24	review under such section; and

- 1 (iv) comply with any other require-2 ments specified by the appropriate Sec-3 retary.
 - Any failure of a group health plan or health insurance issuer to provide a covered individual with timely notice of a decision in a reconsideration as specified in this section shall constitute an affirmation of the adverse coverage determination and the plan or issuer shall submit the case file to the qualified external appeal entity under section 106 within 24 hours of expiration of the deadline otherwise applicable.
 - (3) Provision of oral notice with written confirmation in case of expedited treatment ment.—If a group health plan or health insurance issuer grants a request for expedited treatment under subsection (c), the plan or issuer may first provide notice of the decision in the reconsideration orally within the deadlines established under subsection (b)(3) and then shall mail written confirmation of the decision within 2 business days of the date of oral notification.
 - (4) Affirmation of an adverse coverage determination under expedited treatment.—

1 If, as a result of its reconsideration, the plan or 2 issuer affirms, in whole or in part, a coverage deter-3 mination that is adverse to the covered individual and the reconsideration received expedited treatment 5 under subsection (c), the plan or issuer shall submit 6 the case file (including the written notice of the deci-7 sion in the reconsideration) to the qualified external 8 appeal entity as expeditiously as the covered individ-9 ual's health condition requires, but in no case later 10 than within 24 hours of its affirmation. The plan or 11 issuer shall make reasonable and diligent efforts to 12 assist in gathering and forwarding information to 13 the qualified external appeal entity.

(5) NOTIFICATION OF INDIVIDUAL.—If the plan or issuer refers the matter to an qualified external appeal entity under paragraph (2) or (4), it shall concurrently notify the individual (or an authorized representative of the individual) of that action.

19 SEC. 106. EXTERNAL APPEALS (REVIEWS).

- 20 (a) REVIEW BY QUALIFIED EXTERNAL APPEAL EN-21 TITY.—
- 22 (1) IN GENERAL.—If a qualified external appeal 23 entity obtains a case file under section 105(d) or 24 under paragraph (2) and determines that such ap-25 peal is not so supported but—

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1	(A) there is a significant financial amount
2	in controversy (as defined by the Secretary); or
3	(B) the appeal involves services for the di-
4	agnosis, treatment, or management of an ill-
5	ness, disability, or condition which the entity
6	finds, in accordance with standards established
7	by the entity and approved by the Secretary,
8	constitutes a condition that could seriously
9	jeopardize the covered individual's life, health,
10	or ability to regain or maintain maximum func-
11	tion or (in the case of a child under the age of
12	6) development;
13	the entity shall review and resolve under this section
14	any remaining issues in dispute.
15	(2) Request for review.—
16	(A) In general.—A party to a reconsid-
17	ered determination under section 105 that re-
18	ceives notice of an unfavorable determination
19	under section 105(d) may request a review of
20	such determination by a qualified external ap-
21	peal entity under this section.
22	(B) Time for request.—To request such
23	a review, such party shall submit an oral or
24	written request directly to the plan or issuer
25	(or, if applicable, to the entity that the plan or

issuer has designated as responsible for makingthe determination).

- (C) If Review is requested.—If a party provides the plan or issuer (or such an entity) with notice of a request for such review, the plan or issuer (or such entity) shall submit the case file to the qualified external appeal entity as expeditiously as the covered individual's health condition requires, but in no case later than 2 business days from the date the plan or issuer (or entity) receives such request. The plan or issuer (or entity) shall make reasonable and diligent efforts to assist in gathering and forwarding information to the qualified external appeal entity.
- (3) Notice and timing for review.—The qualified external appeal entity shall establish and apply rules for the timing and content of notices for reviews under this section (including appropriate expedited treatment of reviews under this section) that are similar to the applicable requirements for timing and content of notices in the case of reconsiderations under subsections (b), (c), and (d) of section 105.
- (4) Parties.—The parties to the review by a qualified external appeal entity under this section

1	shall be the same parties listed in section 105(a)(4)
2	who qualified during the plan's or issuer's reconsid-
3	eration, with the addition of the plan or issuer.
4	(b) General Elements of External Appeals.—
5	(1) Contract with qualified external ap-
6	PEAL ENTITY.—
7	(A) Contract requirement.—Subject to
8	subparagraph (B), the external appeal review
9	under this section of a determination of a plan
10	or issuer shall be conducted under a contract
11	between the plan or issuer and 1 or more quali-
12	fied external appeal entities.
13	(B) ELIGIBILITY FOR DESIGNATION AS EX-
14	TERNAL REVIEW ENTITY.—Entities eligible to
15	conduct reviews brought under this subsection
16	shall include—
17	(i) any State licensed or credentialed
18	external review entity;
19	(ii) a State agency established for the
20	purpose of conducting independent exter-
21	nal reviews; and
22	(iii) an independent, external entity
23	that contracts with the appropriate Sec-
24	retary.
25	(C) Licensing and credentialing.—

1	(i) In General.—In licensing or
2	credentialing entities described in subpara-
3	graph (B)(i), the State agent shall use li-
4	censing and certification procedures devel-
5	oped by the State in consultation with the
6	National Association of Insurance Commis-
7	sioners.
8	(ii) Special rule.—In the case of a
9	State that—
10	(I) has not established such li-
11	censing or credentialing procedures
12	within 24 months of the date of enact-
13	ment of this Act, the State shall li-
14	cense or credential such entities in ac-
15	cordance with procedures developed by
16	the Secretary; or
17	(II) refuses to designate such en-
18	tities, the Secretary shall license or
19	credential such entities.
20	(D) QUALIFICATIONS.—An entity (which
21	may be a governmental entity) shall meet the
22	following requirements in order to be a qualified
23	external appeal entity:
24	(i) There is no real or apparent con-
25	flict of interest that would impede the en-

1	tity from conducting external appeal activi-
2	ties independent of the plan or issuer.
3	(ii) The entity conducts external ap-
4	peal activities through clinical peers (as de-
5	fined in section $2(c)(2)$.
6	(iii) The entity has sufficient medical,
7	legal, and other expertise and sufficient
8	staffing to conduct external appeal activi-
9	ties for the plan or issuer on a timely basis
10	consistent with subsection (a)(3).
11	(iv) The entity meets such other re-
12	quirements as the appropriate Secretary
13	may impose.
14	(E) Limitation on Plan or issuer se-
15	LECTION.—If an applicable authority permits
16	more than 1 entity to qualify as a qualified ex-
17	ternal appeal entity with respect to a group
18	health plan or health insurance issuer and the
19	plan or issuer may select among such qualified
20	entities, the applicable authority—
21	(i) shall assure that the selection proc-
22	ess will not create any incentives for quali-
23	fied external appeal entities to make a de-
24	cision in a biased manner; and

1	(ii) shall implement procedures for au-
2	diting a sample of decisions by such enti-
3	ties to assure that no such decisions are
4	made in a biased manner.
5	(F) OTHER TERMS AND CONDITIONS.—
6	The terms and conditions of a contract under
7	this paragraph shall be consistent with the
8	standards the appropriate Secretary shall estab-
9	lish to assure that there is no real or apparent
10	conflict of interest in the conduct of external
11	appeal activities. Such contract shall provide
12	that the direct costs of the process (not includ-
13	ing costs of representation of a covered individ-
14	ual or other party) shall be paid by the plan or
15	issuer, and not by the covered individual.
16	(2) Elements of Process.—An external ap-
17	peal process under this section shall be conducted
18	consistent with standards established by the appro-
19	priate Secretary that include at least the following:
20	(A) Fair process; de novo determina-
21	TION.—The process shall provide for a fair, de
22	novo determination.
23	(B) Opportunity to submit evidence,
24	HAVE REPRESENTATION, AND MAKE ORAL

1	PRESENTATION.—Any party to a review under
2	this section—
3	(i) may submit and review evidence
4	related to the issues in dispute,
5	(ii) may use the assistance or rep-
6	resentation of 1 or more individuals (any
7	of whom may be an attorney), and
8	(iii) may make an oral presentation.
9	(C) Provision of Information.—The
10	plan or issuer involved shall provide timely ac-
11	cess to all its records relating to the matter
12	being reviewed under this section and to all pro-
13	visions of the plan or health insurance coverage
14	(including any coverage manual) relating to the
15	matter.
16	(3) Admissible evidence.—In addition to
17	personal health and medical information supplied
18	with respect to an individual whose claim for bene-
19	fits has been appealed and the opinion of the indi-
20	vidual's treating physician or health care profes-
21	sional, an external appeals entity shall take into con-
22	sideration the following evidence:
23	(A) The results of studies that meet pro-
24	fessionally recognized standards of validity and

1	replicability or that have been published in
2	peer-reviewed journals.
3	(B) The results of professional consensus
4	conferences conducted or financed in whole or
5	in part by one or more government agencies.
6	(C) Practice and treatment guidelines pre-
7	pared or financed in whole or in part by govern-
8	ment agencies.
9	(D) Government-issued coverage and treat-
10	ment policies.
11	(E) To the extent that the entity deter-
12	mines it to be free of any conflict of interest—
13	(i) the opinions of individuals who are
14	qualified as experts in one or more fields
15	of health care which are directly related to
16	the matters under appeal, and
17	(ii) the results of peer reviews con-
18	ducted by the plan or issuer involved.
19	(c) Notice of Determination by External Ap-
20	PEAL ENTITY.—
21	(1) RESPONSIBILITY FOR THE NOTICE.—After
22	the qualified external appeal entity has reviewed and
23	resolved the determination that has been appealed,
24	such entity shall mail a notice of its final decision
25	to the parties.

1	(2) CONTENT OF THE NOTICE.—The notice de-
2	scribed in paragraph (1) shall—
3	(A) describe the specific reasons for the
4	entity's decisions; and
5	(B) comply with any other requirements
6	specified by the appropriate Secretary.
7	(d) Effect of Determination.—A final decision
8	by the qualified external appeal entity after a review of
9	the determination that has been appealed is final and
10	binding on the group health plan or the health insurance
11	issuer.
12	Subtitle B—Consumer Information
13	SEC. 111. HEALTH PLAN INFORMATION.
14	(a) Disclosure Requirement.—
15	(1) Group Health Plans.—A group health
16	plan shall—
17	(A) provide to participants and bene-
18	ficiaries at the time of initial coverage under
19	the plan (or the effective date of this section, in
20	the case of individuals who are participants or
21	beneficiaries as of such date), at least annually
22	thereafter, and at the beginning of any open en-
23	rollment period provided under the plan, the in-
24	formation described in subsection (b) in printed
25	form:

- 1 (B) provide to participants and bene-2 ficiaries information in printed form on mate-3 rial changes in the information described in 4 paragraphs (1), (2)(A), (2)(B), (3)(A), (6), and 5 (7) of subsection (b), or a change in the health 6 insurance issuer through which coverage is pro-7 vided, within a reasonable period of (as speci-8 fied by the Secretary, but not later than 30 9 days after) the effective date of the changes; 10 and
 - (C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsections (b) and (c) in printed form.
 - (2) Health insurance issuers.—A health insurance issuer in connection with the provision of health insurance coverage shall—
 - (A) provide to individuals enrolled under such coverage at the time of enrollment, and at least annually thereafter, (and to plan administrators of group health plans in connection with which such coverage is offered) the information described in subsection (b) in printed form;

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- (B) provide to enrollees and such plan administrators information in printed form on material changes in the information described in paragraphs (1), (2)(A), (2)(B), (3)(A), (6), and (7) of subsection (b), or a change in the health insurance issuer through which coverage is provided, within a reasonable period of (as specified by the Secretary, but not later than 30 days after) the effective date of the changes; and
 - (C) upon request, make available to the applicable authority, to individuals who are prospective enrollees, to plan administrators of group health plans that may obtain such coverage, and to the public the information described in subsections (b) and (c) in printed form.
 - (3) Exemption authority.—Upon application of one or more group health plans or health insurance issuers, the appropriate Secretary, under procedures established by such Secretary, may grant an exemption to one or more plans or issuers from compliance with one or more of the requirements of paragraph (1) or (2). Such an exemption may be granted for plans and issuers as a class with similar

- characteristics, such as private fee-for-service plans described in section 1859(b)(2) of the Social Security Act.
- 4 (4) ESTABLISHMENT OF INTERNET SITE.—The
 5 appropriate Secretaries shall provide for the estab6 lishment of 1 or more sites on the Internet to pro7 vide technical support and information concerning
 8 the rights of participants, beneficiaries, and enrollees
 9 under this title.
- 10 (b) Information Provided.—The information de-11 scribed in this subsection with respect to a group health 12 plan or health insurance coverage offered by a health in-13 surance issuer includes the following:
- 14 (1) SERVICE AREA.—The service area of the plan or issuer.
 - (2) Benefits.—Benefits offered under the plan or coverage, including—
 - (A) covered benefits, including benefits for preventive services, benefit limits, and coverage exclusions, any optional supplemental benefits under the plan or coverage and the terms and conditions (including premiums or cost-sharing) for such supplemental benefits, and any out-of-area coverage;

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1	(B) cost sharing, such as premiums
2	deductibles, coinsurance, and copayment
3	amounts, including any liability for balance bill-
4	ing, any maximum limitations on out of pocket
5	expenses, and the maximum out of pocket costs
6	for services that are provided by nonparticipat-
7	ing providers or that are furnished without
8	meeting the applicable utilization review re-
9	quirements;
10	(C) the extent to which benefits may be ob-
11	tained from nonparticipating providers, and any
12	supplemental premium or cost-sharing in so ob-
13	taining such benefits;
14	(D) the extent to which a participant, ben-
15	eficiary, or enrollee may select from among par-
16	ticipating providers and the types of providers
17	participating in the plan or issuer network;
18	(E) process for determining experimental
19	coverage or coverage in cases of investigational
20	treatments and clinical trials; and
21	(F) use of a prescription drug formulary
22	(3) Access.—A description of the following:
23	(A) The number, mix, and distribution of
24	health care providers under the plan or cov-

erage.

- 1 (B) The procedures for participants, bene-2 ficiaries, and enrollees to select, access, and 3 change participating primary and specialty pro-4 viders.
 - (C) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.
 - (D) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 122(a)(2)(B).
 - (E) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information described in this subsection and subsection (c) to such individuals, including the provision of information in a language other than English if 5 percent of the number of participants, beneficiaries, and enrollees communicate in that language instead of English, and including the availability of interpreters, audio tapes, and information in

1	braille to meet the needs of people with special
2	communications needs.
3	(4) Out-of-area coverage.—Out-of-area cov-
4	erage provided by the plan or issuer.
5	(5) Emergency coverage.—Coverage of
6	emergency services, including—
7	(A) the appropriate use of emergency serv-
8	ices, including use of the 911 telephone system
9	or its local equivalent in emergency situations
10	and an explanation of what constitutes an
11	emergency situation;
12	(B) the process and procedures of the plan
13	or issuer for obtaining emergency services; and
14	(C) the locations of (i) emergency depart-
15	ments, and (ii) other settings, in which plan
16	physicians and hospitals provide emergency
17	services and post-stabilization care.
18	(6) Prior authorization rules.—Rules re-
19	garding prior authorization or other review require-
20	ments that could result in noncoverage or non-
21	payment.
22	(7) Grievance and appeals procedures.—
23	All appeal or grievance rights and procedures under
24	the plan or coverage, including the method for filing
25	grievances and the time frames and circumstances

for acting on grievances and appeals, the name, address, and telephone number of the applicable authority with respect to the plan or issuer, and the availability of assistance through an ombudsman to individuals in relation to group health plans and health insurance coverage.

- (8) QUALITY ASSURANCE.—A summary description of the data on quality indicators and measures submitted under section 112(a) for the plan or issuer, including a summary description of the data on process and outcome satisfaction of participants, beneficiaries, and enrollees (including data on individual voluntary disenrollment and grievances and appeals) described in section 112(b)(3)(D), and notice that information comparing such indicators and measures for different plans and issuers is available through the Agency for Health Care Policy and Research.
- (9) Summary of provider financial incentives.—A summary description of the information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

- 1 (10) Information on Issuer.—Notice of appropriate mailing addresses and telephone numbers
 3 to be used by participants, beneficiaries, and enroll4 ees in seeking information or authorization for treat5 ment.
 - (11) Information on Licensure.—Information on the licensure, certification, or accreditation status of the plan or issuer.
 - (12) AVAILABILITY OF TECHNICAL SUPPORT AND INFORMATION.—Notice that technical support and information concerning the rights of participants, beneficiaries, and enrollees under this title are available from the Secretary of Labor (in the case of group health plans) or the Secretary of Health and Human Services (in the case of health insurance issuers), including the telephone numbers and mailing address of the regional offices of the appropriate Secretary and the Internet address to obtain such information and support.
 - (13) ADVANCE DIRECTIVES AND ORGAN DONA-TION DECISIONS.—Information regarding the use of advance directives and organ donation decisions under the plan or coverage.
 - (14) Participating provider list.—A list of current participating health care providers for the

- relevant geographic area, including the name, address and telephone number of each provider.
- 3 (15) AVAILABILITY OF INFORMATION ON RE-4 QUEST.—Notice that the information described in 5 subsection (c) is available upon request and how and 6 where (such as the telephone number and Internet 7 website) such information may be obtained.
- 8 (c) Information Made Available Upon Re-9 Quest.—The information described in this subsection is 10 the following:
 - (1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under section 102(a), including under any drug formulary program under section 123(b).
 - (2) Grievance and appeals information.—
 Information on the number of grievances and internal and external appeals and on the disposition in the aggregate of such matters, including information on the reasons for the disposition of external appeal cases.
 - (3) METHOD OF COMPENSATION.—A summary description as to the method of compensation of participating health care professionals and health care

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- facilities, including information on the types of financial payment incentives (described in section
 1852(j)(4) of the Social Security Act) provided by
 the plan or issuer under the coverage and on the
 proportion of participating health care professionals
 who are compensated under each type of incentive
 under the plan or coverage.
 - (4) CONFIDENTIALITY POLICIES AND PROCE-DURES.—A description of the policies and procedures established to carry out section 112.
 - (5) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions, including the specific prescription medications included in any formulary and any provisions for obtaining off-formulary medications.
 - (6) Additional information on participating ing providers.—For each current participating health care provider described in subsection (b)(14)—
- 20 (A) the licensure or accreditation status of 21 the provider;
 - (B) to the extent possible, an indication of whether the provider is available to accept new patients;

- 1 (C) in the case of medical personnel, the 2 education, training, speciality qualifications or 3 certification, speciality focus, affiliation ar-4 rangements, and specialty board certification (if 5 any) of the provider; and
 - (D) any measures of consumer satisfaction and quality indicators for the provider.
 - (7) Percentage of Premiums used for Benefits (Loss-Ratios).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).
 - (8) QUALITY INFORMATION DEVELOPED.—
 Quality information on processes and outcomes developed as part of an accreditation or licensure process for the plan or issuer to the extent the information is publicly available.

(d) Form of Disclosure.—

(1) Uniformity.—Information required to be disclosed under this section shall be provided in accordance with uniform, national reporting standards specified by the Secretary, after consultation with

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- applicable State authorities, so that prospective enrollees may compare the attributes of different issuers and coverage offered within an area within a type of coverage. Such information shall be provided in an accessible format that is understandable to the average participant, beneficiary, or enrollee involved.
- (2) Information into handbook.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from making the information under subsections (b) and (c) available to participants, beneficiaries, and enrollees through an enrollee handbook or similar publication.
- (3) Updating participating provider in-FORMATION.—The information on participating care providers described in subsections health (b)(14) and (c)(6) shall be updated within such reasonable period as determined appropriate by the Secretary. A group health plan or health insurance issuer shall be considered to have complied with the provisions of such subsection if the plan or issuer provides the directory or listing of participating providers to participants and beneficiaries or enrollees once a year and such directory or listing is updated within such a reasonable period to reflect any mate-

- rial changes in participating providers. Nothing in this section shall prevent a plan or issuer from changing or updating other information made available under this section.
 - (4) Rule of Mailing to last address.—For purposes of this section, a plan or issuer, in reliance on records maintained by the plan or issuer, shall be deemed to have met the requirements of this section with respect to the disclosure of information to a participant, beneficiary, or enrollee if the plan or issuer transmits the information requested to the participant, beneficiary, or enrollee at the address contained in such records with respect to such participant, beneficiary, or enrollee.

(e) Enrollee Assistance.—

- (1) In General.—Each State that obtains a grant under paragraph (3) shall provide for creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers. Such Ombudsman shall be responsible for at least the following:
- (A) To provide consumers in the State with information about health insurance cov-

- erage options or coverage options offered within group health plan.
 - (B) To provide counseling and assistance to enrollees dissatisfied with their treatment by health insurance issuers and group health plans in regard to such coverage or plans and with respect to grievances and appeals regarding determinations under such coverage or plans.
 - (2) Federal Role.—In the case of any State that does not provide for such an Ombudsman under paragraph (1), the Secretary may provide for the creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers and that is to provide consumers in the State with information about health insurance coverage options or coverage options offered within group health plans.
 - (3) ELIGIBILITY.—To be eligible to serve as a Health Insurance Ombudsman under this section, a not-for-profit organization shall provide assurances that—
 - (A) the organization has no real or perceived conflict of interest in providing advice

1	and assistance to consumers regarding health
2	insurance coverage, and
3	(B) the organization is independent of
4	health insurance issuers, health care providers
5	health care payors, and regulators of health
6	care or health insurance.
7	(4) Authorization of appropriations.—
8	There are authorized to be appropriated to the Sec-
9	retary of Health and Human Services such amounts
10	as may be necessary to provide for grants to States
11	for contracts for Health Insurance Ombudsmer
12	under paragraph (1) or contracts for such Ombuds-
13	men under paragraph (2).
14	(5) Construction.—Nothing in this section
15	shall be construed to prevent the use of other forms
16	of enrollee assistance.
17	(f) Construction.—Nothing in this section shall be
18	construed as requiring public disclosure of individual con-
19	tracts or financial arrangements between a group health
20	plan or health insurance issuer and any provider.
21	SEC. 112. HEALTH CARE QUALITY INFORMATION.
22	(a) Collection and Submission of Information
23	ON QUALITY INDICATORS AND MEASURES.—
24	(1) In general.—A group health plan and a
25	health insurance issuer that offers health insurance

- coverage shall collect and submit to the Director for the Agency for Health Care Policy and Research (in this section referred to as the "Director") aggregate data on quality indicators and measures (as defined in subsection (g)) that includes the minimum uniform data set specified under subsection (b). Such data shall not include patient identifiers.
 - (2) Data sampling methods.—The Director shall develop data sampling methods for the collection of data under this subsection.
 - (3) EXEMPTION AUTHORITY.—The provisions of section 111(a)(3) shall apply to the requirements of paragraph (1) in the same manner as they apply to the requirements referred to in such section.

(b) Minimum Uniform Data Set.—

- (1) IN GENERAL.—The Secretary shall specify (and may from time to time update) by rule the data required to be included in the minimum uniform data set under subsection (a) and the standard format for such data.
- (2) Design.—Such specification shall—
 - (A) take into consideration the different populations served (such as children and individuals with disabilities);

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1	(B) be consistent where appropriate with
2	requirements applicable to Medicare+Choice
3	health plans under 1851(d)(4)(D) of the Social
4	Security Act;
5	(C) take into consideration such dif-
6	ferences in the delivery system among group
7	health plans and health insurance issuers as the
8	Secretary deems appropriate;
9	(D) be consistent with standards adopted
10	to carry out part C of title XI of the Social Se-
11	curity Act; and
12	(E) be consistent where feasible with exist-
13	ing health plan quality indicators and measures
14	used by employers and purchasers.
15	(3) MINIMUM DATA.—The data in such set
16	shall include, to the extent determined feasible by
17	the appropriate Secretary, at least—
18	(A) data on process measures of clinical
19	performance for health care services provided
20	by health care professionals and facilities;
21	(B) data on outcomes measures of morbid-
22	ity and mortality including to the extent fea-
23	sible and appropriate data for pediatric and
24	gender-specific measures; and

1 (C) data on data on satisfaction of such in-2 dividuals, including data on voluntary 3 disenrollment and grievances.

The minimum data set under this paragraph shall be established by the appropriate Secretaries using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.

(c) Dissemination of Information.—

- (1) IN GENERAL.—The Director shall publicly disseminate (through printed media and the Internet) information on the aggregate data submitted under this section.
- (2) Formats.—The information shall be disseminated in a manner that provides for a comparison of health care quality among different group health plans and health insurance issuers, with appropriate differentiation by delivery system. In disseminating the information, the Director may reference an appropriate benchmark (or benchmarks) for performance with respect to specific quality indicators and measures (or groups of such measures).
- 22 (d) HEALTH CARE QUALITY RESEARCH AND INFOR-23 MATION.—The Secretary of Health and Human Services, 24 acting through the Director, shall conduct and support re-25 search demonstration projects, evaluations, and the dis-

1	semination of information with respect to measurement,
2	status, improvement, and presentation of quality indica-
3	tors and measures and other health care quality informa-
4	tion.
5	(e) National Reports on Health Care Qual-
6	ITY.—
7	(1) Report on National Goals.—Not later
8	than 18 months after the date of enactment of this
9	Act, and every 2 years thereafter, the Secretary of
10	Health and Human Services shall prepare and sub-
11	mit to the appropriate committees of Congress and
12	the President a report that—
13	(A) establishes national goals for the im-
14	provement of the quality of health care; and
15	(B) contains recommendations for achiev-
16	ing the national goals established under para-
17	graph (1).
18	(2) Report on health related topics.—
19	Not later than 30 months after the date of enact-
20	ment of this Act and every 2 years thereafter, such
21	Secretary shall prepare and submit to Congress and
22	the President a report that addresses at least 1 of

the following (or a related matter):

1	(A) The availability, applicability, and ap-
2	propriateness of information to consumers re-
3	garding the quality of their health care.
4	(B) The state of information systems and
5	data collecting capabilities for measuring and
6	reporting on quality indicators.
7	(C) The impact of quality measurement on
8	access to and the cost of medical care.
9	(D) Barriers to continuous quality im-
10	provement in medical care.
11	(E) The state of health care quality meas-
12	urement research and development.
13	(f) Authorization of Appropriations.—There
14	are authorized to be appropriated \$25,000,000 for each
15	fiscal year (beginning with fiscal year 2000) to carry out
16	this section. Any such amounts appropriated for a fiscal
17	year shall remain available, without fiscal year limitation,
18	until expended.
19	(g) Quality Indicators and Measures De-
20	FINED.—For purposes of this section, the term "quality
21	indicators and measures" means structural characteris-
22	tics, patient-encounter data, and the subsequent health
23	status change of a patient as a result of health care serv-
24	ices provided by health care professionals and facilities.

1	SEC. 113. CONFIDENTIALITY AND ACCURACY OF ENROLLEE
2	RECORDS.
3	A group health plan or a health insurance issuer shall
4	establish procedures with respect to medical records or
5	other health information maintained regarding partici-
6	pants, beneficiaries, and enrollees to safeguard the privacy
7	of any individually identifiable information about them.
8	SEC. 114. QUALITY ASSURANCE.
9	(a) Requirement.—A group health plan, and a
10	health insurance issuer that offers health insurance cov-
11	erage, shall establish and maintain an ongoing, internal
12	quality assurance and continuous quality improvement
13	program that meets the requirements of subsection (b).
14	(b) Program Requirements.—The requirements of
15	this subsection for a quality improvement program of a
16	plan or issuer are as follows:
17	(1) Administration.—The plan or issuer has
18	an identifiable unit with responsibility for adminis-
19	tration of the program.
20	(2) Written plan.—The plan or issuer has a
21	written plan for the program that is updated annu-
22	ally and that specifies at least the following:
23	(A) The activities to be conducted.
24	(B) The organizational structure.
25	(C) The duties of the medical director.

1	(D) Criteria and procedures for the assess-
2	ment of quality.
3	(3) Systematic review.—The program pro-
4	vides for systematic review of the type of health
5	services provided, consistency of services provided
6	with good medical practice, and patient outcomes.
7	(4) QUALITY CRITERIA.—The program—
8	(A) uses criteria that are based on per-
9	formance and patient outcomes where feasible
10	and appropriate;
11	(B) includes criteria that are directed spe-
12	cifically at meeting the needs of at-risk popu-
13	lations and covered individuals with chronic
14	conditions or severe illnesses, including gender-
15	specific criteria and pediatric-specific criteria
16	where available and appropriate;
17	(C) includes methods for informing covered
18	individuals of the benefit of preventive care and
19	what specific benefits with respect to preventive
20	care are covered under the plan or coverage
21	and
22	(D) makes available to the public a de-
23	scription of the criteria used under subpara-
24	graph (A).

1	(5) System for identifying.—The program
2	has procedures for identifying possible quality con-
3	cerns by providers and enrollees and for remedial ac-
4	tions to correct quality problems, including written
5	procedures for responding to concerns and taking
6	appropriate corrective action.
7	(6) Data analysis.—The program provides,
8	using data that include the data collected under sec-
9	tion 112, for an analysis of the plan's or issuer's
10	performance on quality measures.
11	(7) Drug utilization review.—The program
12	provides for a drug utilization review program
13	which—
14	(A) encourages appropriate use of prescrip-
15	tion drugs by participants, beneficiaries, and
16	enrollees and providers, and
17	(B) takes appropriate action to reduce the
18	incidence of improper drug use and adverse
19	drug reactions and interactions.
20	(c) Deeming.—For purposes of subsection (a), the
21	requirements of—
22	(1) subsection (b) (other than paragraph (5))
23	are deemed to be met with respect to a health insur-
24	ance issuer that is a qualified health maintenance

1	organization (as defined in section 1310(c) of the
2	Public Health Service Act); or
3	(2) subsection (b) are deemed to be met with
4	respect to a health insurance issuer that is accred-
5	ited by a national accreditation organization that the
6	Secretary certifies as applying, as a condition of cer-
7	tification, standards at least a stringent as those re-
8	quired for a quality improvement program under
9	subsection (b).
10	(d) Variation Permitted.—The Secretary may
11	provide for variations in the application of the require-
12	ments of this section to group health plans and health in-
13	surance issuers based upon differences in the delivery sys-
14	tem among such plans and issuers as the Secretary deems
15	appropriate.
16	(e) Consultation in Medical Policies.—A group
17	health plan, and health insurance issuer that offers health
18	insurance coverage, shall consult with participating physi-
19	cians (if any) regarding the plan's or issuer's medical pol-
20	icy, quality, and medical management procedures.
21	Subtitle C—Patient Protection
22	Standards
23	SEC. 121. EMERGENCY SERVICES.
24	(a) Coverage of Emergency Services.—

- 1 (1) IN GENERAL.—If a group health plan, or
 2 health insurance coverage offered by a health insur3 ance issuer, provides any benefits with respect to
 4 emergency services (as defined in paragraph (2)(B)),
 5 the plan or issuer shall cover emergency services fur6 nished under the plan or coverage—
 7 (A) without the need for any prior author-
 - (A) without the need for any prior authorization determination;
 - (B) whether or not the health care provider furnishing such services is a participating provider with respect to such services;
 - (C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating health care provider the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider; and
 - (D) without regard to any other term or condition of such plan or coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income

Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) Definitions.—In this section:

- (A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—
 The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.
- (B) EMERGENCY SERVICES.—The term "emergency services" means—
 - (i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical

1	condition (as defined in subparagraph
2	(A)), and
3	(ii) within the capabilities of the staff
4	and facilities available at the hospital, such
5	further medical examination and treatment

6 as are required under section 1867 of such

7 Act to stabilize the patient.

8 (b) Reimbursement for Maintenance Care and Post-Stabilization Care.—In the case of services 10 (other than emergency services) for which benefits are available under a group health plan, or under health insur-12 ance coverage offered by a health insurance issuer, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) if the services are maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act 19 (relating to promoting efficient and timely coordination of 20 21 appropriate maintenance and post-stabilization care of an enrollee after an enrollee has been determined to be stable), in accordance with regulations established to carry out such section.

1	SEC. 122. ENROLLEE CHOICE OF HEALTH PROFESSIONALS
2	AND PROVIDERS.
3	(a) Choice of Personal Health Profes-
4	SIONAL.—
5	(1) Primary care.—A group health plan, and
6	a health insurance issuer that offers health insur-
7	ance coverage, shall permit each participant, bene-
8	ficiary, and enrollee—
9	(A) to receive primary care from any par-
10	ticipating primary care provider who is avail-
11	able to accept such individual, and
12	(B) in the case of a participant, bene-
13	ficiary, or enrollee who has a child who is also
14	covered under the plan or coverage, to des-
15	ignate a participating physician who specializes
16	in pediatrics as the child's primary care pro-
17	vider.
18	(2) Specialists.—
19	(A) In general.—Subject to subpara-
20	graph (B), a group health plan and a health in-
21	surance issuer that offers health insurance cov-
22	erage shall permit each participant, beneficiary,
23	or enrollee to receive medically necessary or ap-
24	propriate specialty care, pursuant to appro-

priate referral procedures, from any qualified

1	participating health care provider who is avail-
2	able to accept such individual for such care.
3	(B) Limitation.—Subparagraph (A) shall
4	not apply to specialty care if the plan or issuer
5	clearly informs participants, beneficiaries, and
6	enrollees of the limitations on choice of partici-
7	pating providers with respect to such care.
8	(b) Specialized Services.—
9	(1) Obstetrical and gynecological
10	CARE.—
11	(A) In general.—If a group health plan,
12	or a health insurance issuer in connection with
13	the provision of health insurance coverage, re-
14	quires or provides for a participant, beneficiary,
15	or enrollee to designate a participating primary
16	care provider, and an individual who is female
17	has not designated a participating physician
18	specializing in obstetrics and gynecology as a
19	primary care provider, the plan or issuer—
20	(i) may not require authorization or a
21	referral by the individual's primary care
22	provider or otherwise for coverage of rou-
23	tine gynecological care (such as preventive
24	women's health examinations) and preg-

nancy-related services provided by a par-

1	ticipating health care professional who spe-
2	cializes in obstetrics and gynecology to the
3	extent such care is otherwise covered, and
4	(ii) may treat the ordering of other
5	gynecological care by such a participating
6	physician as the authorization of the pri-
7	mary care provider with respect to such
8	care under the plan or coverage.
9	(B) Construction.—Nothing in subpara-
10	graph (A)(ii) shall waive any requirements of
11	coverage relating to medical necessity or appro-
12	priateness with respect to coverage of gyneco-
13	logical care so ordered.
14	(2) Specialty care.—
15	(A) Specialty care for covered serv-
16	ICES.—
17	(i) In general.—If—
18	(I) an individual is a participant
19	or beneficiary under a group health
20	plan or an enrollee who is covered
21	under health insurance coverage of-
22	fered by a health insurance issuer,
23	(II) the individual has a condi-
24	tion or disease of sufficient serious-

1	ness and complexity to require treat-
2	ment by a specialist, and
3	(III) benefits for such treatment
4	are provided under the plan or cov-
5	erage,
6	the plan or issuer shall make or provide for
7	a referral to a specialist who is available
8	and accessible to provide the treatment for
9	such condition or disease.
10	(ii) Specialist defined.—For pur-
11	poses of this paragraph, the term "special-
12	ist" means, with respect to a condition, a
13	health care practitioner, facility, or center
14	(such as a center of excellence) that has
15	adequate expertise through appropriate
16	training and experience (including, in the
17	case of a child, appropriate pediatric exper-
18	tise) to provide high quality care in treat-
19	ing the condition.
20	(iii) Care under referral.—A
21	group health plan or health insurance
22	issuer may require that the care provided
23	to an individual pursuant to such referral
24	under clause (i) be—

1	(I) pursuant to a treatment plan,
2	only if the treatment plan is developed
3	by the specialist and approved by the
4	plan or issuer, in consultation with
5	the designated primary care provider
6	or specialist and the individual (or the
7	individual's designee), and
8	(II) in accordance with applicable
9	quality assurance and utilization re-
10	view standards of the plan or issuer.
11	Nothing in this paragraph shall be con-
12	strued as preventing such a treatment plan
13	for an individual from requiring a special-
14	ist to provide the primary care provider
15	with regular updates on the specialty care
16	provided, as well as all necessary medical
17	information.
18	(iv) Referrals to participating
19	PROVIDERS.—A group health plan or
20	health insurance issuer is not required
21	under clause (i) to provide for a referral to
22	a specialist that is not a participating pro-
23	vider, unless the plan or issuer does not
24	have an appropriate specialist that is avail-

able and accessible to treat the individual's

1	condition	and	that	is	a	participating	pro-
2	vider with	resp	ect to	sı	acl	n treatment.	

- (v) TREATMENT OF NONPARTICIPAT-ING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to clause (i), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.
- (B) Specialists as primary care providers.—

(i) In GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in clause (iii)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and

1	specialty care. If such an individual's care
2	would most appropriately be coordinated
3	by such a specialist, such plan or issuer
4	shall refer the individual to such specialist.
5	(ii) Treatment as primary care
6	PROVIDER.—Such specialist shall be per-
7	mitted to treat the individual without a re-
8	ferral from the individual's primary care
9	provider and may authorize such referrals,
10	procedures, tests, and other medical serv-
11	ices as the individual's primary care pro-
12	vider would otherwise be permitted to pro-
13	vide or authorize, subject to the terms of
14	the treatment plan (referred to in subpara-
15	graph (A)(iii)(I)).
16	(iii) Ongoing special condition
17	DEFINED.—In this subparagraph, the term
18	"special condition" means a condition or
19	disease that—
20	(I) is life-threatening, degenera-
21	tive, or disabling, and
22	(II) requires specialized medical
23	care over a prolonged period of time.
24	(iv) Terms of Referral.—The pro-
25	visions of clauses (iii) through (v) of sub-

paragraph (A) apply with respect to referrals under clause (i) of this subparagraph in the same manner as they apply to referrals under subparagraph (A)(i).

(C) STANDING REFERRALS.—

(i) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist.

(ii) Terms of referral.—The provisions of clauses (iii) through (v) of subparagraph (A) apply with respect to referrals under clause (i) of this subparagraph

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1	in the same manner as they apply to refer-
2	rals under subparagraph (A)(i).
3	(c) Continuity of Care.—
4	(1) In general.—
5	(A) TERMINATION OF PROVIDER.—If a
6	contract between a group health plan, or a
7	health insurance issuer in connection with the
8	provision of health insurance coverage, and a
9	health care provider is terminated (as defined
10	in subparagraph (C)), or benefits or coverage
11	provided by a health care provider are termi-
12	nated because of a change in the terms of pro-
13	vider participation in a group health plan, and
14	an individual who is a participant, beneficiary,
15	or enrollee in the plan or coverage is under-
16	going a course of treatment from the provider
17	at the time of such termination, the plan or
18	issuer shall—
19	(i) notify the individual on a timely
20	basis of such termination, and
21	(ii) subject to paragraph (3), permit
22	the individual to continue or be covered
23	with respect to the course of treatment
24	with the provider during a transitional pe-

riod (provided under paragraph (2)) if the

plan or issuer is notified orally or in writing of the facts and circumstances concerning the course of treatment.

- (B)TREATMENT OF TERMINATION CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of subparagraph (A) (and the succeeding provisions of this section) shall apply under the group health plan in the same manner as if there had been a direct contract between the group health plan and the provider that had been terminated, but only with respect to benefits that are covered under the group health plan after the contract termination.
- (C) TERMINATION.—In this section, the term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

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1 (2) Transitional Period.— 2 (A) IN GENERAL.—Except as provided in 3 subparagraphs (B) through (D), the transi-4 tional period under this subsection shall extend 5 for at least 90 days from the date of the notice 6 described in paragraph (1)(A)(i) of the provid-7 er's termination. 8 (B) Institutional care.—The transi-9 tional period under this subsection for institu-10 tional or inpatient care from a provider shall 11 extend until the discharge or termination of the 12 period of institutionalization and also shall in-13 clude institutional care provided within a rea-14 sonable time of the date of termination of the 15 provider status. (C) Pregnancy.—If— 16 17 (i) a participant, beneficiary, or en-18 rollee has entered the second trimester of 19 pregnancy at the time of a provider's ter-20 mination of participation, and (ii) the provider was treating the 21 22 pregnancy before date of the termination, 23 the transitional period under this subsection

with respect to provider's treatment of the

pregnancy shall extend through the provision of

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1	post-partum care directly related to the deliv-
2	ery.
3	(D) TERMINAL ILLNESS.—If—
4	(i) a participant, beneficiary, or en-
5	rollee was determined to be terminally ill
6	(as determined under section
7	1861(dd)(3)(A) of the Social Security Act)
8	at the time of a provider's termination of
9	participation, and
10	(ii) the provider was treating the ter-
11	minal illness before the date of termi-
12	nation,
13	the transitional period under this subsection
14	shall extend for the remainder of the individ-
15	ual's life for care directly related to the treat-
16	ment of the terminal illness, but in no case is
17	the transitional period required to extend for
18	longer than 180 days.
19	(3) Permissible terms and conditions.—A
20	group health plan or health insurance issuer may
21	condition coverage of continued treatment by a pro-
22	vider under paragraph (1)(A)(ii) upon the provider
23	agreeing to the following terms and conditions:
24	(A) The provider agrees to accept reim-
25	bursement from the plan or issuer and individ-

ual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in paragraph (1)(B), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in paragraph (1)(A) had not been terminated.

- (B) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under subparagraph (A) and to provide to such plan or issuer necessary medical information related to the care provided.
- (C) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding utilization review and referrals, and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

1	(4) Construction.—Nothing in this sub-
2	section shall be construed to require the coverage of
3	benefits which would not have been covered if the
4	provider involved remained a participating provider.
5	(d) Protection Against Involuntary
6	DISENROLLMENT BASED ON CERTAIN CONDITIONS.—
7	(1) In general.—Subject to paragraph (2), a
8	group health plan and a health insurance issuer in
9	connection with the provision of health insurance
10	coverage may not disenroll an individual under the
11	plan or coverage because the individual's behavior is
12	considered disruptive, unruly, abusive, or uncoopera-
13	tive to the extent that the individual's continued en-
14	rollment under the coverage seriously impairs the
15	plan's or issuer's ability to furnish covered services
16	if the circumstances for the individual's behavior is
17	directly related to diminished mental capacity, severe
18	and persistent mental illness, or a serious childhood
19	mental and emotional disorder.
20	(2) Exception.—Paragraph (1) shall not
21	apply if the behavior engaged in directly threatens
22	bodily injury to any person.
23	(e) General Access.—
24	(1) In general.—Each group health plan, and

each health insurance issuer offering health insur-

1 ance coverage, that provides benefits, in whole or in 2 part, through participating health care providers 3 shall have (in relation to the coverage) a sufficient number, distribution, and variety of qualified partici-5 pating health care providers to ensure that all cov-6 ered health care services, including specialty serv-7 ices, will be available and accessible in a timely man-8 ner to all participants, beneficiaries, and enrollees 9 under the plan or coverage.

(2) Treatment of certain providers.—The qualified health care providers under paragraph (1) may include Federally qualified health centers, rural health clinics, migrant health centers, high-volume, disproportionate share hospitals, and other essential community providers located in the service area of the plan or issuer and shall include such providers if necessary to meet the standards established to carry out such subsection.

19 SEC. 123. ACCESS TO APPROVED SERVICES.

- 20 (a) Coverage for Individuals Participating in21 Approved Clinical Trials.—
- 22 (1) Coverage.—
- 23 (A) IN GENERAL.—If a group health plan, 24 or health insurance issuer that is providing 25 health insurance coverage, provides coverage to

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1	a qualified individual (as defined in paragraph
2	(2)), the plan or issuer—
3	(i) may not deny the individual par-
4	ticipation in the clinical trial referred to in
5	paragraph (2)(B);
6	(ii) subject to paragraph (3), may not
7	deny (or limit or impose additional condi-
8	tions on) the coverage of routine patient
9	costs for items and services furnished in
10	connection with participation in the trial;
11	and
12	(iii) may not discriminate against the
13	individual on the basis of the enrollee's
14	participation in such trial.
15	(B) Exclusion of Certain Costs.—For
16	purposes of subparagraph (A)(ii), routine pa-
17	tient costs do not include the cost of the tests
18	or measurements conducted primarily for the
19	purpose of the clinical trial involved.
20	(C) Use of in-network providers.—If
21	one or more participating providers is partici-
22	pating in a clinical trial, nothing in subpara-
23	graph (A) shall be construed as preventing a
24	plan or issuer from requiring that a qualified
25	individual participate in the trial through such

1	a participating provider if the provider will ac-
2	cept the individual as a participant in the trial.
3	(2) Qualified individual defined.—For
4	purposes of paragraph (1), the term "qualified indi-
5	vidual" means an individual who is a participant or
6	beneficiary in a group health plan, or who is an en-
7	rollee under health insurance coverage, and who
8	meets the following conditions:
9	(A)(i) The individual has a life-threatening
10	or serious illness for which no standard treat-
11	ment is effective.
12	(ii) The individual is eligible to participate
13	in an approved clinical trial according to the
14	trial protocol with respect to treatment of such
15	illness.
16	(iii) The individual's participation in the
17	trial offers meaningful potential for significant
18	clinical benefit for the individual.
19	(B) Either—
20	(i) the referring physician is a partici-
21	pating health care professional and has
22	concluded that the individual's participa-
23	tion in such trial would be appropriate
24	based upon the individual meeting the con-
25	ditions described in subparagraph (A); or

1	(ii) the participant, beneficiary, or en-
2	rollee provides medical and scientific infor-
3	mation establishing that the individual's
4	participation in such trial would be appro-
5	priate based upon the individual meeting
6	the conditions described in subparagraph
7	(A).
8	(3) Payment.—
9	(A) IN GENERAL.—Under this subsection a
10	group health plan or health insurance issuer
11	shall provide for payment for routine patient
12	costs described in paragraph (1)(A) but is not
13	required to pay for costs of items and services
14	that are reasonably expected (as determined by
15	the Secretary) to be paid for by the sponsors of
16	an approved clinical trial.
17	(B) PAYMENT RATE.—In the case of cov-
18	ered items and services provided by—
19	(i) a participating provider, the pay-
20	ment rate shall be at the agreed upon rate,
21	or
22	(ii) a nonparticipating provider, the
23	payment rate shall be at the rate the plan
24	or issuer would normally pay for com-
25	parable services under clause (i).

1	(4) Approved clinical trial defined.—
2	(A) IN GENERAL.—In this subsection, the
3	term "approved clinical trial" means a clinical
4	research study or clinical investigation approved
5	and funded (which may include funding through
6	in-kind contributions) by one or more of the fol-
7	lowing:
8	(i) The National Institutes of Health
9	(ii) A cooperative group or center of
10	the National Institutes of Health.
11	(iii) Either of the following if the con-
12	ditions described in subparagraph (B) are
13	met:
14	(I) The Department of Veterans
15	Affairs.
16	(II) The Department of Defense.
17	(B) Conditions for departments.—
18	The conditions described in this subparagraph,
19	for a study or investigation conducted by a De-
20	partment, are that the study or investigation
21	has been reviewed and approved through a sys-
22	tem of peer review that the Secretary
23	determines—
24	(i) to be comparable to the system of
25	peer review of studies and investigations

1	used by the National Institutes of Health,
2	and
3	(ii) assures unbiased review of the
4	highest scientific standards by qualified in-
5	dividuals who have no interest in the out-
6	come of the review.
7	(5) Construction.—Nothing in this sub-
8	section shall be construed to limit a plan's or
9	issuer's coverage with respect to clinical trials.
10	(b) Access to Prescription Drugs.—
11	(1) In general.—If a group health plan, or
12	health insurance issuer that offers health insurance
13	coverage, provides benefits with respect to prescrip-
14	tion drugs but the coverage limits such benefits to
15	drugs included in a formulary, the plan or issuer
16	shall—
17	(A) ensure participation of participating
18	physicians and pharmacists in the development
19	of the formulary; and
20	(B) disclose to providers and, disclose upon
21	request under section 111(c)(5) to participants,
22	beneficiaries, and enrollees, the nature of the
23	formulary restrictions; and
24	(C) consistent with the standards for a uti-
25	lization review program under section 102(a).

- provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.
- 4 (2) Construction.—Nothing in this sub5 section shall be construed as requiring a group
 6 health plan (or health insurance issuer in connection
 7 with health insurance coverage) to provide any cov8 erage of prescription drugs or as preventing such a
 9 plan or issuer from negotiating higher cost-sharing
 10 in the case a non-formulary alternative is provided
 11 under paragraph (1)(C).

12 SEC. 124. NONDISCRIMINATION IN DELIVERY OF SERVICES.

- 13 (a) Application to Delivery of Services.—Subject to subsection (b), a group health plan, and health in-14 15 surance issuer in relation to health insurance coverage, may not discriminate against a participant, beneficiary, or 16 enrollee in the delivery of health care services consistent with the benefits covered under the plan or coverage or as required by law based on race, color, ethnicity, national 19 20 origin, religion, sex, age, mental or physical disability, sex-21 ual orientation, genetic information, or source of payment. 22 (b) Construction.—Nothing in subsection (a) shall
- 23 be construed as relating to the eligibility to be covered,
- 24 or the offering (or guaranteeing the offer) of coverage,
- 25 under a plan or health insurance coverage, the application

- 1 of any pre-existing condition exclusion consistent with ap-
- 2 plicable law, or premiums charged under such plan or cov-
- 3 erage. To the extent that health care providers are per-
- 4 mitted under State and Federal law to prioritize the ad-
- 5 mission or treatment of patients based on such patients'
- 6 individual religious affiliation, group health plans and
- 7 health insurance issuers may reflect those priorities in re-
- 8 ferring patients to such providers.

9 SEC. 125. PROHIBITION OF INTERFERENCE WITH CERTAIN

- 10 MEDICAL COMMUNICATIONS.
- 11 (a) IN GENERAL.—An organization on behalf of a
- 12 group health plan (as described in subsection (a)(2)) or
- 13 a health insurance issuer shall not penalize (financially or
- 14 otherwise) a health care professional for advocating on be-
- 15 half of his or her patient or for providing information or
- 16 referral for medical care (as defined in section 2791(a)(2)
- 17 of the Public Health Service Act) consistent with the
- 18 health care needs of the patient and with the code of ethi-
- 19 cal conduct, professional responsibility, conscience, medi-
- 20 cal knowledge, and license of the health care professional.
- 21 (b) Construction.—Nothing in subsection (a) shall
- 22 be construed as requiring a health insurance issuer or a
- 23 group health plan to pay for medical care not otherwise
- 24 paid for or covered by the plan provided by nonparticipat-
- 25 ing health care professionals, except in those instances and

- 1 to the extent that the issuer or plan would normally pay
- 2 for such medical care.
- 3 (c) Assistance and Support.—A group health plan
- 4 or a health insurance issuer shall not prohibit or otherwise
- 5 restrict a health care professional from providing letters
- 6 of support to, or in any way assisting, enrollees who are
- 7 appealing a denial, termination, or reduction of service in
- 8 accordance with the procedures under subtitle A.

9 SEC. 126. PROVIDER INCENTIVE PLANS.

- 10 (a) Prohibition of Transfer of Indemnifica-
- 11 TION.—
- 12 (1) In general.—No contract or agreement
- between a group health plan or health insurance
- issuer (or any agent acting on behalf of such a plan
- or issuer) and a health care provider shall contain
- any provision purporting to transfer to the health
- 17 care provider by indemnification or otherwise any li-
- ability relating to activities, actions, or omissions of
- the plan, issuer, or agent (as opposed to the pro-
- vider).
- 21 (2) Nullification.—Any contract or agree-
- ment provision described in paragraph (1) shall be
- 23 null and void.
- (b) Prohibition of Improper Physician Incen-
- 25 TIVE PLANS.—

- 1 (1) IN GENERAL.—A group health plan and a
 2 health insurance issuer offering health insurance
 3 coverage may not operate any physician incentive
 4 plan (as defined in subparagraph (B) of section
 5 1876(i)(8) of the Social Security Act) unless the re6 quirements described in subparagraph (A) of such
 7 section are met with respect to such a plan.
- 8 (2) Application.—For purposes of carrying 9 out paragraph (1), any reference insection 10 1876(i)(8) of the Social Security Act to the Sec-11 retary, an eligible organization, or an individual en-12 rolled with the organization shall be treated as a ref-13 erence to the applicable authority, a group health 14 plan or health insurance issuer, respectively, and a 15 participant, beneficiary, or enrollee with the plan or 16 organization, respectively.

17 SEC. 127. PROVIDER PARTICIPATION.

- 18 (a) In General.—A group health plan and a health
 19 insurance issuer that offers health insurance coverage
 20 shall, if it provides benefits through participating health
 21 care professionals, have a written process for the selection
 22 of participating health care professionals under the plan
 23 or coverage. Such process shall include—
- 24 (1) minimum professional requirements;

- 1 (2) providing notice of the rules regarding participation;
 - (3) providing written notice of participation decisions that are adverse to professionals; and
- 5 (4) providing a process within the plan or issuer 6 for appealing such adverse decisions, including the 7 presentation of information and views of the profes-8 sional regarding such decision.
- 9 (b) Verification of Background.—Such process
 10 shall include verification of a health care provider's license
 11 and a history of suspension or revocation.
- 12 (c) RESTRICTION.—Such process shall not use a 13 high-risk patient base or location of a provider in an area 14 with residents with poorer health status as a basis for ex-15 cluding providers from participation.

(d) General Nondiscrimination.—

(1) In General.—Subject to paragraph (2), such process shall not discriminate with respect to selection of a health care professional to be a participating health care provider, or with respect to the terms and conditions of such participation, based on the professional's race, color, religion, sex, national origin, age, sexual orientation, or disability (consistent with the Americans with Disabilities Act of 1990).

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1 (2) Rules.—The appropriate Secretary may
2 establish such definitions, rules, and exceptions as
3 may be appropriate to carry out paragraph (1), tak4 ing into account comparable definitions, rules, and
5 exceptions in effect under employment-based non6 discrimination laws and regulations that relate to
7 each of the particular bases for discrimination de8 scribed in such paragraph.

9 SEC. 128. REQUIRED COVERAGE FOR APPROPRIATE HOS-

- 10 PITAL STAY FOR MASTECTOMIES AND LYMPH
 11 NODE DISSECTIONS FOR THE TREATMENT OF
 12 BREAST CANCER.
- (a) Coverage of Inpatient Care for Surgical
 Treatment of Breast Cancer.—
 - (1) In General.—A group health plan, and a health insurance issuer providing health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the surgical treatment of breast cancer (including a mastectomy, lumpectomy, or lymph node dissection for the treatment of breast cancer) is provided for a period of time as is determined by the attending physician, in his or her professional judgment consistent with generally accepted principles of profes-

- sional medical practice, in consultation with the patient, to be medically necessary or appropriate.
 - (2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician in consultation with the patient determine that a shorter period of hospital stay is medically necessary or appropriate.

(b) No Authorization Required.—

- (1) IN GENERAL.—An attending physician shall not be required to obtain authorization from the plan or issuer for prescribing any length of stay in connection with a mastectomy, a lumpectomy, or a lymph node dissection for the treatment of breast cancer.
- (2) Prenotification.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from requiring prenotification of an inpatient stay referred to in this section if such requirement is consistent with terms and conditions applicable to other inpatient benefits under the plan or health insurance coverage, except that the provision of such inpatient stay benefits shall not be contingent upon such notification.

1	(e) Prohibitions.—A group health plan and a
2	health insurance issuer offering health insurance coverage
3	may not—
4	(1) deny to a patient eligibility, or continued
5	eligibility, to enroll or to renew coverage under the
6	terms of the plan or coverage, solely for the purpose
7	of avoiding the requirements of this section;
8	(2) provide monetary payments or rebates to in-
9	dividuals to encourage such individuals to accept less
10	than the minimum protections available under this
11	section;
12	(3) penalize or otherwise reduce or limit the re-
13	imbursement of an attending provider because such
14	provider provided care to an individual participant,
15	beneficiary, or enrollee in accordance with this sec-
16	tion;
17	(4) provide incentives (monetary or otherwise)
18	to an attending provider to induce such provider to
19	provide care to an individual participant, beneficiary,
20	or enrollee in a manner inconsistent with this sec-
21	tion; and
22	(5) subject to subsection (d)(2), restrict benefits
23	for any portion of a period within a hospital length

of stay required under subsection (a) in a manner

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1	which is less favorable than the benefits provided for
2	any preceding portion of such stay.
3	(d) Rules of Construction.—
4	(1) In general.—Nothing in this section shall
5	be construed to require a patient who is a partici-
6	pant, beneficiary, or enrollee—
7	(A) to undergo a mastectomy or lymph
8	node dissection in a hospital; or
9	(B) to stay in the hospital for a fixed pe-
10	riod of time following a mastectomy or lymph
11	node dissection.
12	(2) Cost sharing.—Nothing in this section
13	shall be construed as preventing a group health plan
14	or issuer from imposing deductibles, coinsurance, or
15	other cost-sharing in relation to benefits for hospital
16	lengths of stay in connection with a mastectomy or
17	lymph node dissection for the treatment of breast
18	cancer under the plan or health insurance coverage
19	except that such coinsurance or other cost-sharing
20	for any portion of a period within a hospital length
21	of stay required under subsection (a) may not be
22	greater than such coinsurance or cost-sharing for
23	any preceding portion of such stay.
24	(3) Level and type of reimbursements.—

Nothing in this section shall be construed to prevent

- a group health plan or a health insurance issuer
- 2 from negotiating the level and type of reimburse-
- 3 ment with a provider for care provided in accordance
- 4 with this section.

5 SEC. 129. PROMOTING GOOD MEDICAL PRACTICE.

- 6 (a) Prohibiting Arbitrary Limitations or Con-
- 7 DITIONS FOR THE PROVISION OF SERVICES.—
- 8 (1) IN GENERAL.—A group health plan, and a 9 health insurance issuer in connection with the provi-10 sion of health insurance coverage, may not arbitrar-11 ily interfere with or alter the decision of the treating 12 physician regarding the manner or setting in which 13 particular services are delivered if the services are 14 medically necessary or appropriate for treatment or 15 diagnosis to the extent that such treatment or diag-

nosis is otherwise a covered benefit.

- (2) Construction.—Paragraph (1) shall not be construed as prohibiting a plan or issuer from limiting the delivery of services to one or more health care providers within a network of such providers.
- (3) Manner or setting Defined.—In paragraph (1), the term "manner or setting" means the location of treatment, such as whether treatment is provided on an inpatient or outpatient basis, and the

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1	duration of treatment, such as the number of days
2	in a hospital. Such term does not include the cov-
3	erage of a particular service or treatment.
4	(b) No Change in Coverage.—Subsection (a) shall
5	not be construed as requiring coverage of particular serv-
6	ices the coverage of which is otherwise not covered under
7	the terms of the plan or coverage or from conducting utili-
8	zation review activities consistent with this subsection.
9	(c) Medical Necessity or Appropriateness De-
10	FINED.—In subsection (a), the term "medically necessary
11	or appropriate" means, with respect to a service or benefit,
12	a service or benefit which is consistent with generally ac-
13	cepted principles of professional medical practice.
14	Subtitle D—Enhanced Enforcement
	Authonity
15	Authority
15 16	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY,
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16	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY,
16 17	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY, INJUNCTIVE RELIEF AUTHORITY, AND IN-
16 17 18	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY, INJUNCTIVE RELIEF AUTHORITY, AND IN- CREASED CIVIL MONEY PENALTY AUTHORITY
16 17 18	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY, INJUNCTIVE RELIEF AUTHORITY, AND IN- CREASED CIVIL MONEY PENALTY AUTHORITY FOR SECRETARY OF HEALTH AND HUMAN
16 17 18 19 20	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY, INJUNCTIVE RELIEF AUTHORITY, AND IN- CREASED CIVIL MONEY PENALTY AUTHORITY FOR SECRETARY OF HEALTH AND HUMAN SERVICES FOR VIOLATIONS OF PATIENT PRO-
16 17 18 19 20 21	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY, INJUNCTIVE RELIEF AUTHORITY, AND IN- CREASED CIVIL MONEY PENALTY AUTHORITY FOR SECRETARY OF HEALTH AND HUMAN SERVICES FOR VIOLATIONS OF PATIENT PRO- TECTION STANDARDS.
16 17 18 19 20 21	SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY, INJUNCTIVE RELIEF AUTHORITY, AND INCREASED CIVIL MONEY PENALTY AUTHORITY FOR SECRETARY OF HEALTH AND HUMAN SERVICES FOR VIOLATIONS OF PATIENT PROTECTION STANDARDS. (a) INVESTIGATIONS AND REPORTING AUTHORITY.—

1	sions of sections 2707 and 2753, respectively, of
2	such Act (as added by title II of this Act)—
3	(A) the Secretary of Health and Human
4	Services shall have the same authorities with
5	respect to compelling health insurance issuers
6	to produce information and to conducting inves-
7	tigations in cases of violations of such provi-
8	sions as the Secretary of Labor has under sec-
9	tion 504 of the Employee Retirement Income
10	Security Act of 1974 with respect to violations
11	of title I of such Act; and
12	(B) section 504(c) of the Employee Retire-
13	ment Income Security Act of 1974 shall apply
14	to investigations conducted under paragraph (1)
15	in the same manner as it applies to investiga-
16	tions conducted under title I of such Act.
17	(2) Reporting authority.—In exercising au-
18	thority under paragraph (1), the Secretary may
19	require—
20	(A) States that have indicated an intention
21	to assume authority under section 2722(a)(1)
22	or 2761(a) of the Public Health Service Act to
23	report to the Secretary on enforcement efforts
24	undertaken to assure compliance with the re-

1	quirements of sections 2707 and 2753, respec-
2	tively, of such Act; and
3	(B) health insurance issuers to submit re-
4	ports to assure compliance with such require-
5	ments.
6	(b) AUTHORITY FOR INJUNCTIVE RELIEF.—In addi-
7	tion to the authority referred to in subsection (a), the Sec-
8	retary of Health and Human Services has the same au-
9	thority with respect to enforcement of the provisions of
10	this title as the Secretary of Labor has under subsection
11	(a)(5) of section 502 of the Employee Retirement Income
12	Security Act of 1974 (as applied without regard to sub-
13	section (b) of that section) and the related provisions of
14	part 5 of subtitle B of title I of such Act with respect
15	to enforcement of such title I of such Act.
16	(c) Increase in Civil Money Penalties.—
17	(1) In general.—In the case of a civil money
18	penalty that may be imposed under section
19	2722(b)(2) or 2761(b) of the Public Health Service
20	Act with respect to a failure to meet the provisions
21	of sections 2707 and 2753, respectively, of such Act,
22	the maximum amount of penalty otherwise provided
23	under section 2722(b)(2)(C)(i) of such Act may, not-
24	withstanding the amounts specified in such section,

1	and subject to paragraph (2), be up to the greatest
2	of the following:
3	(A) Failures involving unreasonable
4	DENIAL OR DELAY IN BENEFITS IMPACTING ON
5	LIFE OR HEALTH.—In the case of a failure that
6	results in an unreasonable denial or delay in
7	benefits that has seriously jeopardized (or has
8	substantial likelihood of seriously jeopardizing)
9	the individual's life, health, or ability to regain
10	or maintain maximum function or (in the case
11	of a child under the age of 6) development, the
12	greater of the following:—
13	(i) Pattern or practice fail-
14	URE.—If the failure reflects a pattern or
15	practice of wrongful conduct, \$250,000
16	plus the amount (if any) determined under
17	paragraph (2).
18	(ii) Other failures.—In the case of
19	a failure that does not reflect a pattern or
20	practice of wrongful conduct, \$50,000 for
21	each individual involved, plus the amount
22	(if any) determined under paragraph (2).
23	(B) Other failures.—In the case of a
24	failure not described in subparagraph (A), the
25	greater of the following:

1	(i) Pattern and practice fail-
2	URES.—In the case of a failure that re-
3	flects a pattern or practice of wrongful
4	conduct \$50,000, plus the amount (if any)
5	determined under paragraph (2).
6	(ii) Other failures.—In the case of
7	a failure that does not reflect a pattern or
8	practice of wrongful conduct, \$10,000 for
9	each individual involved, plus the amount
10	(if any) determined under paragraph (2).
11	(2) Continuing failure without correc-
12	TION.—In the case of a failure which is not cor-
13	rected within the first week beginning with the date
14	on which the failure is established, the maximum
15	amount of the penalty under paragraph (1) shall be
16	increased by \$10,000 for each full succeeding week
17	in which the failure is not so corrected.
18	(d) Authorization of Appropriations.—In addi-
19	tion to any other amounts authorized to be appropriated,
20	there are authorized to be appropriated to the Secretary
21	of Health and Human Services such sums as may be nec-
22	essary to carry out this section.

1	SEC. 142. AUTHORITY FOR SECRETARY OF LABOR TO IM-
2	POSE CIVIL PENALTIES FOR VIOLATIONS OF
3	PATIENT PROTECTION STANDARDS.
4	(a) In General.—Section 502(c) of the Employee
5	Retirement Income Security Act of 1974 (29 U.S.C.
6	1132(c)) is amended by redesignating paragraphs (6) and
7	(7) as paragraphs (7) and (8), respectively, and by insert-
8	ing after paragraph (5) the following new paragraph:
9	"(6)(A) The Secretary may assess a civil penalty
10	against a person acting in the capacity of a fiduciary of
11	a group health plan (as defined in 733(a)) so as to cause
12	a violation of section 714.
13	"(B) Subject to subparagraph (C), the maximum
14	amount which may be assessed under subparagraph (A)
15	is the greatest of the following:
16	"(i) In the case of a failure that results in an
17	unreasonable denial or delay in benefits that seri-
18	ously jeopardized (or has substantial likelihood of se-
19	riously jeopardizing) the individual's life, health, or
20	ability to regain or maintain maximum function or
21	(in the case of a child under the age of 6) develop-
22	ment, the greater of the following:
23	"(I) If the failure reflects a pattern or
24	practice of wrongful conduct, \$250,000, plus
25	the amount (if any) determined under subpara-
26	graph (C).

1	"(II) In the case of a failure that does not
2	reflect a pattern or practice of wrongful con-
3	duct, \$50,000 for each individual involved, plus
4	the amount (if any) determined under subpara-
5	graph (C).
6	"(ii) In the case of a failure not described in
7	clause (i), the greater of the following:
8	"(I) In the case of a failure that reflects
9	a pattern or practice of wrongful conduct
10	\$50,000, plus the amount (if any) determined
11	under subparagraph (C).
12	"(II) In the case of a failure that does not
13	reflect a pattern or practice of wrongful con-
14	duct, \$10,000 for each individual involved, plus
15	the amount (if any) determined under subpara-
16	graph (C).
17	"(C) In the case of a failure which is not corrected
18	within the first week beginning with the date on which
19	the failure is established, the maximum amount of the
20	penalty under subparagraph (B) shall be increased by
21	\$10,000 for each full succeeding week in which the failure
22	is not so corrected.".
23	(b) Conforming Amendment.—Section 502(a)(6)
24	of such Act (29 U.S.C. 1132(a)(6)) is amended by striking

- 1 "paragraph (2), (4), (5), or (6)" and inserting "paragraph
- 2 (2), (4), (5), (6), or (7)".
- 3 (c) Authorization of Appropriations.—In addi-
- 4 tion to any other amounts authorized to be appropriated,
- 5 there are authorized to be appropriated to the Secretary
- 6 of Labor such sums as may be necessary to carry out the
- 7 amendments made by this section.

8 TITLE II—PATIENT PROTECTION

9 STANDARDS UNDER PUBLIC

10 **HEALTH SERVICE ACT**

- 11 SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND
- 12 GROUP HEALTH INSURANCE COVERAGE.
- 13 (a) IN GENERAL.—Subpart 2 of part A of title
- 14 XXVII of the Public Health Service Act, as amended by
- 15 the Omnibus Consolidated and Emergency Supplemental
- 16 Appropriations Act, 1999 (Public Law 105-277), is
- 17 amended by adding at the end the following new section:
- 18 "SEC. 2707. PATIENT PROTECTION STANDARDS.
- 19 "(a) IN GENERAL.—Each group health plan shall
- 20 comply with patient protection requirements under title I
- 21 of the Promoting Responsible Managed Care Act of 1999,
- 22 and each health insurance issuer shall comply with patient
- 23 protection requirements under such title with respect to
- 24 group health insurance coverage it offers, and such re-

- 1 quirements shall be deemed to be incorporated into this
- 2 subsection.
- 3 "(b) NOTICE.—A group health plan shall comply with
- 4 the notice requirement under section 711(d) of the Em-
- 5 ployee Retirement Income Security Act of 1974 with re-
- 6 spect to the requirements referred to in subsection (a) and
- 7 a health insurance issuer shall comply with such notice
- 8 requirement as if such section applied to such issuer and
- 9 such issuer were a group health plan.".
- 10 (b) Conforming Amendment.—Section
- 11 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
- 12 is amended by inserting "(other than section 2707)" after
- 13 "requirements of such subparts".
- 14 (c) Reference to Enhanced Enforcement Au-
- 15 Thority.—For provisions providing for enhanced author-
- 16 ity to enforce the patient protection requirements of title
- 17 I under the Public Health Service Act, see section 141.
- 18 SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-
- 19 ANCE COVERAGE.
- 20 Part B of title XXVII of the Public Health Service
- 21 Act, as amended by the Omnibus Consolidated and Emer-
- 22 gency Supplemental Appropriations Act, 1999 (Public
- 23 Law 105-277), is amended by inserting after section 2753
- 24 the following new section:

1	"SEC	2753	PATIENT	PROTECTION	STANDARDS
1	SEC.	4100.	PALIENT	PROTECTION	STANDARDS.

2	4	'(a)	In	GEN	ERAL.—	-Each	health	n insurance	issuer
3	shall	com	ply	with	patient	protec	etion r	requirements	under

- 4 title I of the Promoting Responsible Managed Care Act
- 5 of 1999 with respect to individual health insurance cov-
- 6 erage it offers, and such requirements shall be deemed to
- 7 be incorporated into this subsection.
- 8 "(b) Notice.—A health insurance issuer under this
- 9 part shall comply with the notice requirement under sec-
- 10 tion 711(d) of the Employee Retirement Income Security
- 11 Act of 1974 with respect to the requirements of such title
- 12 as if such section applied to such issuer and such issuer
- 13 were a group health plan.".

14 TITLE III—PATIENT PROTEC-

- 15 TION STANDARDS UNDER
- 16 THE EMPLOYEE RETIREMENT
- 17 INCOME SECURITY ACT OF
- 18 **1974**
- 19 SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-
- 20 ARDS TO GROUP HEALTH PLANS AND GROUP
- 21 HEALTH INSURANCE COVERAGE UNDER THE
- 22 EMPLOYEE RETIREMENT INCOME SECURITY
- 23 ACT OF 1974.
- 24 (a) IN GENERAL.—Subpart B of part 7 of subtitle
- 25 B of title I of the Employee Retirement Income Security
- 26 Act of 1974, as amended by the Omnibus Consolidated

- 1 and Emergency Supplemental Appropriations Act, 1999
- 2 (Public Law 105–277), is amended by adding at the end
- 3 the following new section:
- 4 "SEC. 714. PATIENT PROTECTION STANDARDS.
- 5 "(a) IN GENERAL.—Subject to subsection (b), a
- 6 group health plan (and a health insurance issuer offering
- 7 group health insurance coverage in connection with such
- 8 a plan) shall comply with the requirements of title I of
- 9 the Promoting Responsible Managed Care Act of 1999 (as
- 10 in effect as of the date of the enactment of such Act),
- 11 and such requirements shall be deemed to be incorporated
- 12 into this subsection.
- 13 "(b) Plan Satisfaction of Certain Require-
- 14 MENTS.—
- 15 "(1) Satisfaction of Certain Require-
- 16 Ments through insurance.—For purposes of
- subsection (a), insofar as a group health plan pro-
- vides benefits in the form of health insurance cov-
- erage through a health insurance issuer, the plan
- shall be treated as meeting the following require-
- 21 ments of title I of the Promoting Responsible Man-
- aged Care Act of 1999 with respect to such benefits
- and not be considered as failing to meet such re-
- 24 quirements because of a failure of the issuer to meet
- such requirements so long as the plan sponsor or its

1	representatives did not cause such failure by the
2	issuer:
3	"(A) Section 121 (relating to access to
4	emergency care).
5	"(B) Section 122 (relating to choice of
6	providers).
7	"(C) Section 122(b) (relating to specialized
8	services).
9	"(D) Section 122(c)(1)(A) (relating to con-
10	tinuity in case of termination of provider con-
11	tract) and section 122(c)(1)(B) (relating to
12	continuity in case of termination of issuer con-
13	tract), but only insofar as a replacement issuer
14	assumes the obligation for continuity of care.
15	"(E) Section 123(a) (relating to coverage
16	for individuals participating in approved clinical
17	trials.)
18	"(F) Section 123(b) (relating to access to
19	needed prescription drugs).
20	"(G) Section 122(e) (relating to adequacy
21	of provider network).
22	"(H) Subtitle B (relating to consumer in-
23	formation).
24	"(2) Information.—With respect to informa-
25	tion required to be provided or made available under

health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

"(3) GRIEVANCE AND INTERNAL APPEALS.—
With respect to the grievance system and internal appeals process required to be established under sections 102 and 103 of such Act, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such system and process (and is not liable for the issuer's failure to provide for such system and process), if the issuer is obligated to provide for (and provides for) such system and process.

"(4) External appeals.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal

1	entity for the conduct of external appeal activities in
2	accordance with section 106 of such Act, the plan
3	shall be treated as meeting the requirement of such
4	section and is not liable for the entity's failure to
5	meet any requirements under such section.
6	"(5) Application to prohibitions.—Pursu-
7	ant to rules of the Secretary, if a health insurance
8	issuer offers health insurance coverage in connection
9	with a group health plan and takes an action in vio-
10	lation of any of the following sections of such Act,
11	the group health plan shall not be liable for such
12	violation unless the plan caused such violation:
13	"(A) Section 124 (relating to non-
14	discrimination in delivery of services).
15	"(B) Section 125 (relating to prohibition
16	of interference with certain medical communica-
17	tions).
18	"(C) Section 126 (relating to provider in-
19	centive plans).
20	"(D) Section 102(b) (relating to providing
21	medically necessary care).
22	"(6) Construction.—Nothing in this sub-
23	section shall be construed to affect or modify the re-
24	sponsibilities of the fiduciaries of a group health

plan under part 4 of subtitle B.

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- 1 (b) Satisfaction of ERISA Claims Procedure
- 2 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
- 3 1133) is amended by inserting "(a)" after "Sec. 503."
- 4 and by adding at the end the following new subsection:
- 5 "(b) In the case of a group health plan (as defined
- 6 in section 733) compliance with the requirements of sub-
- 7 title D (and section 113) of title I of the Promoting Re-
- 8 sponsible Managed Care Act of 1999 in the case of a
- 9 claims denial shall be deemed compliance with subsection
- 10 (a) with respect to such claims denial.".
- 11 (c) Conforming Amendments.—(1) Section 732(a)
- 12 of such Act (29 U.S.C. 1185(a)) is amended by striking
- 13 "section 711" and inserting "sections 711 and 714".
- 14 (2) The table of contents in section 1 of such Act
- 15 is amended by inserting after the item relating to section
- 16 713 the following new item:
 - "Sec. 714. Patient protection standards.".
- 17 (3) Section 502(b)(3) of such Act (29 U.S.C.
- 18 1132(b)(3)) is amended by inserting "(other than section
- 19 144(b))" after "part 7".
- 20 (d) Reference to Enhanced Enforcement Au-
- 21 THORITY.—For provisions providing for enhanced author-
- 22 ity to enforce the patient protection requirements of title
- 23 I under the Employee Retirement Income Security Act of
- 24 1974, see section 142.

1	SEC. 302. ENFORCEMENT FOR ECONOMIC LOSS CAUSED BY
2	COVERAGE DETERMINATIONS.
3	(a) In General.—Section 502(c) of the Employee
4	Retirement Income Security Act of 1974 (29 U.S.C.
5	1132), as amended by section 142(a) of this Act, is
6	amended by redesignating paragraphs (7) and (8) as para-
7	graphs (8) and (9), respectively, and by inserting after
8	paragraph (6) the following new paragraph:
9	"(7)(A) In any case in which—
10	"(i) a coverage determination (as defined in
11	section 101(a)(2) of the Promoting Responsible
12	Managed Care Act of 1999) under a group health
13	plan (as defined in section 503(b)(8)) is not made
14	on a timely basis or is made on such a basis but is
15	not made in accordance with the terms of the plan,
16	this title, or title I of such Act, and
17	"(ii) a participant or beneficiary suffers per-
18	sonal injury (including loss of life, health, or the
19	ability to regain or maintain maximum function or
20	(in the case of a child under the age of 6) develop-
21	ment) as a result of such coverage determination,
22	any person or persons who are responsible under the terms
23	of the plan for the making of such coverage determination
24	are liable to the aggrieved participant or beneficiary for

25 the amount of the economic loss suffered by the partici-

26 pant or beneficiary caused by such coverage determina-

- 1 tion. Any question of fact in any cause of action under
- 2 this paragraph shall be based on the preponderance of the
- 3 evidence after de novo review.
- 4 "(B) For purposes of subparagraph (A), the term
- 5 'economic loss' means any pecuniary loss (including the
- 6 loss of earnings or other benefits related to employment,
- 7 medical expense loss, replacement services loss, loss due
- 8 to death, burial costs, and loss of business or employment
- 9 opportunities) caused by the coverage determination. Such
- 10 term does not include punitive damages or damages for
- 11 pain and suffering, inconvenience, emotional distress,
- 12 mental anguish, loss of consortium, injury to reputation,
- 13 humiliation, and other nonpecuniary losses.
- 14 "(C) Nothing in this paragraph shall be construed as
- 15 requiring exhaustion of administrative process in the case
- 16 of severe bodily injury or death.
- 17 "(D) For purposes of subparagraph (A), the term
- 18 'personal injury' means a physical injury and includes an
- 19 injury arising out of the treatment (or failure to treat)
- 20 a mental illness or disease.".
- 21 (b) Effective Date.—The amendments made by
- 22 subsection (a) apply to coverage determinations made on
- 23 or after the date of the enactment of this Act.

1	TITLE IV—PATIENT PROTEC-
2	TION STANDARDS UNDER
3	THE INTERNAL REVENUE
4	CODE OF 1986
5	SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE
6	OF 1986
7	Subchapter B of chapter 100 of the Internal Revenue
8	Code of 1986 (as amended by section 1531(a) of the Tax-
9	payer Relief Act of 1997) is amended—
10	(1) in the table of sections, by inserting after
11	the item relating to section 9812 the following new
12	item:
	"Sec. 9813. Standard relating to patient protection standards."; and
13	(2) by inserting after section 9812 the follow-
14	ing:
15	"SEC. 9813. STANDARD RELATING TO PATIENT PROTEC-
16	TION STANDARDS.
17	"A group health plan shall comply with the require-
18	ments of title I of the Promoting Responsible Managed
19	Care Act of 1999 (as in effect as of the date of the enact-
20	ment of such Act), and such requirements shall be deemed
21	to be incorporated into this section.".

TITLE V—EFFECTIVE DATES; CO-

2 ORDINATION IN IMPLEMEN-

3 TATION

- 4 SEC. 501. EFFECTIVE DATES.
- 5 (a) Group Health Coverage.—
- 6 (1) IN GENERAL.—Subject to paragraph (2), 7 the amendments made by sections 201(a), 301, and 8 401 (and title I insofar as it relates to such sections) 9 shall apply with respect to group health plans, and 10 health insurance coverage offered in connection with 11 group health plans, for plan years beginning on or 12 after January 1, 2000 (in this section referred to as 13 the "general effective date") and also shall apply to 14 portions of plan years occurring on and after such 15 date.
 - (2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by sections 201(a), 301, and 401 (and title I insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

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1	(A) the date on which the last collective
2	bargaining agreement relating to the plan ter-
3	minates (determined without regard to any ex-
4	tension thereof agreed to after the date of en-
5	actment of this Act), or
6	(B) the general effective date.
7	For purposes of subparagraph (A), any plan amend-
8	ment made pursuant to a collective bargaining
9	agreement relating to the plan which amends the
10	plan solely to conform to any requirement added by
11	this Act shall not be treated as a termination of
12	such collective bargaining agreement.
13	(b) Individual Health Insurance Coverage.—
14	The amendments made by section 202 shall apply with
15	respect to individual health insurance coverage offered,
16	sold, issued, renewed, in effect, or operated in the individ-
17	ual market on or after the general effective date.
18	SEC. 502. COORDINATION IN IMPLEMENTATION.
19	Section 104(1) of Health Insurance Portability and
20	Accountability Act of 1996 is amended by striking "this
21	subtitle (and the amendments made by this subtitle and
22	section 401)" and inserting "the provisions of part 7 of
23	subtitle B of title I of the Employee Retirement Income
24	Security Act of 1974, the provisions of parts A and C of
25	title XXVII of the Public Health Service Act, chapter 100

- 1 of the Internal Revenue Code of 1986, and title I of the
- 2 Promoting Responsible Managed Care Act of 1999".

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